

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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3	WARNER CHILCOTT LABORATORIES	:	2:09-cv-2073-WJM MF
	IRELAND LIMITED, MAYNE PHARMA	:	
4	INTERNATIONAL, PTY, LTD.,	:	
		:	
5	Plaintiffs,	:	
		:	TRANSCRIPT OF PROCEEDINGS
6	v.	:	- Trial -
		:	AFTERNOON SESSION
7	MYLAN PHARMACEUTICALS, INC. and	:	
	MYLAN INC.,	:	
8		:	
	Defendants.	:	
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	WARNER CHILCOTT LABORATORIES	:	2:08-cv-6304-WJM MF
10	IRELAND LIMITED, MAYNE PHARMA	:	2:09-cv-1233-WJM MF
	INTERNATIONAL, PTY, LTD.,	:	
11		:	
	Plaintiffs,	:	
12		:	
	v.	:	
13		:	
	IMPAX LABORATORIES, INC.,	:	
14		:	
	Defendants.	:	
15	- - - - -	:	-x

February 8, 2012
Newark, New Jersey

B E F O R E:

THE HONORABLE WILLIAM J. MARTINI,
UNITED STATES DISTRICT JUDGE

Pursuant to Section 753 Title 28 United States Code, the
following transcript is certified to be an accurate record as
taken stenographically in the above entitled proceedings.

S/WALTER J. PERELLI

WALTER J. PERELLI, CCR, CRR
Official Court Reporter

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1

I N D E X

2

WITNESS

DIRECT

CROSS

REDIRECT

RECROSS

3

ARTHUR H. KIBBE

BY MR. PACELLA

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BY MR. SEPHTON

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TINA DEVRIES

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By Mr. Weisblatt

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By Mr. Scambia

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The record is sealed at page 40, line 17

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the record is unsealed at page 41, line 20

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February 8, 2012

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A F T E R N O O N S E S S I O N

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A R T H U R H. K I B B E, resumes, testifies further as

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follows:

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THE DEPUTY CLERK: Remain seated.

8

THE COURT: My apologies for a Late start. Please be

9

seated.

10

MR. PACELLA: Thank you, your Honor.

11

DIRECT EXAMINATION CONTINUES

12

BY MR. PACELLA:

13

Q Welcome back, Dr. Kibbe.

14

Before the break we were discussing solubilities in

15

the various coatings and the delayed-release coating and your

And just to wrap up, did you prepare a slide to summarize why you believe that Dr. Davies used an appropriate solvent in his treatment method?

A Yes, I did.

MR. PACELLA: Do we have Slide 12.

Q Dr. Kibbe, could you please explain just summarize the basis for your conclusions concerning the solvent?

A Okay. So the mixture of Impax's delayed-release coating beads have variable solubility, each ingredient has a different

WALTER J. PERELLI, C.S.R., OFFICIAL COURT REPORTER, NEWARK, NJ

1 kind of solubility.

2 The HPMC and the HPMCP are not really soluble in 99
3 percent acetone. Polymer dissolution from a complex polymer is
4 a very slow process and it requires vigorous agitation.

5 Dr. Davies used 99 percent acetone to 1 to water, and
6 he swirled it by hand or one of his colleagues swirled it by
7 hand or mixed it by hand in a container. Impax uses a
8 mechanical mixer which creates a vortex, and then adds the
9 powders to that, and they use a more water concentrated solvent
10 of 70 percent acetone and 30 percent water.

11 Q Now, in terms of HPMCP not being soluble in 99 percent
12 acetone, could you point to a specific reference that had data
13 that actually addressed the specific solution or solvent of
14 99-to-1?

15 A No.

16 Q Is it still your belief that 99 percent-to-1 would not be
17 an appropriate solvent to use with HPMCP, HP-50?

18 A Yes, I think you'd be better off with a higher
19 concentration of water.

20 Q All right. Moving on to a slightly different but related
21 topic. What, in your opinion, is the result of Dr. Davies'
22 acetone washing step?

23 A I think that he differentially dissolved some of the
24 ingredients and does not completely dissolve the layer.

25 MR. PACELLA: Could we have Slide 13, please.

1 Q Slide 13, will that assist you in explaining why you
2 believe -- what you believe is happening whether Dr. Davies
3 washes the Impaxed seeds?

4 A Okay. This is an attempt to explain what I think might be
5 occurring. We start off on the left with an intact seed with
6 an intact delayed-release coat. The delayed-release coat, if
7 we looked at it as a cross-section, would have pockets of talc,
8 it would also have a uniform distribution of HPMC and HPMCP,
9 and triethyl citrate. As we start to cash it because, triethyl
10 citrate is soluble in acetone and the acetone will begin to
11 migrate into the coat, triethyl citrate will come out more
12 rapidly than anything else.

13 MR. SEPHTON: Your Honor, just to object this
14 explanation was not in Dr. Kibbe's expert report or at his
15 deposition.

16 MR. PACELLA: Your Honor the differential --

17 THE COURT: Wait a minute. Go ahead, let me hear you,
18 go ahead.

19 MR. PACELLA: Your Honor, it's just a depiction of the
20 description of why the differential solubles as discussed in
21 Dr. Kibbe's expert report is to illustrate that pictorially.
22 No, this diagram does not appear in his expert report, but the
23 basis for this diagram is clearly in his expert report.

24 THE COURT: All right. I'll allow it, overruled.
25 Go ahead.

1 A (Continuing) So what you're seeing, your Honor, is that the
2 coating is beginning to dissolved away and it's not dissolving
3 away uniformly. It swells when it's in contact with.
4 water/acetone mixture. And so some of the talc is sloughing
5 off as part of the polymer leaves. And after time we're left
6 with a layer which still consists of the ingredients that were
7 added when the delayed-released coat was first applied, only
8 it's reduced in size. And then of course when he dries the
9 beads, that layer does then again tighten down.

10 And what I've shown here is that I think most of the
11 triethyl citrate will have left, but we'll still have HPMCP,
12 HPMC and talc. And Dr. Davies actually measured peaks that he
13 said corresponds to the phthalate, which is HPMCP, and talc.

14 Q Now, what do you believe the presence -- let me just back
15 up a step. You understand that Dr. Davies has pointed to talc
16 and the infrared peaks specific to the phthalate group as
17 indicating what he says is a talc-enriched area and an
18 HPMEC-derived material in his alleged sub-coating.

19 A Yes.

20 Q Do you recall that?

21 A I do.

22 Q And what is your opinion as to what the presence of the
23 talc and phthalate specific peaks in his washed pellet
24 experiment indicates?

25 A Well, those are still there. That HPMCP and talc are still

1 in the layer. And therefore, that layer consists principally
2 of the ingredients that were included in Impax's
3 delayed-release coat as it was first applied.

4 Q Now, you might have touched on this previously, I just want
5 to ask one question about Dr. Davies' criticism of you in terms
6 of his acetone wash test.

7 Do you recall that Dr. Davies criticized you because
8 you didn't repeat his expert?

9 A Yes.

10 Q And did you, in fact, repeat his experiment?

11 A No.

12 Q And what was the reason why you didn't repeat his
13 experiment?

14 A I didn't think it was a reasonable experiment that would
15 help us learn anything about the presence of a supposed barrier
16 layer or stabilising layer in the intact Impax product.

17 Q Now, did you prepare a slide to help explain why you
18 believe the presence of the phthalate peak demonstrates the
19 presence of the delayed-release coating remains versus the
20 presence of a stabilising coat?

21 A Yes, I did.

22 MR. PACELLA: Could we have Slide 15. Or 14. 15.

23 THE WITNESS: Okay. These are the two structures for
24 the two polymers, your Honor. This is HPMC on the left, and it
25 has substitutions, either methyl groups or propyl groups.

1 Over here on the right is HPMCP. The "P" is the
2 phthalate, this is a phthalate group. And the phthalate can
3 either be substituted here or this phthalate propyl group can
4 be substituted there. The critical element is the phthalate.
5 The phthalate makes the polymer insoluble in stomach acid and
6 soluble in the intestinal tract, and hence, it causes that
7 polymer to do the work of a delayed-release coat.

8 It's listed as one of the ingredients in the
9 delayed-release coat in the patent, but it can not get out of
10 the way as the barrier coat is supposed to do because it's not
11 HPMC. It's the phthalate attached to HPMC, and thus, an
12 enteric or delayed-release coat.

13 BY MR. PACELLA:

14 Q Now, could you just summarize, if we could look at Slide
15 14, could you summarize why you believe that Dr. Davies'
16 analysis of the Impax seeds doesn't support his conclusion that
17 there's a sub-coating, or the stabilising coat that he
18 described?

19 A Dr. Davies doesn't identify what HPMCP-derived material is,
20 but he has a peak that is the equivalent for HP-50. The
21 analysis identifies the same peak, HPMCP, as it identifies as
22 the peak that he calls the "derived material." And there are
23 other experts in here that talked about that. And the presence
24 of the phthalate establishes nothing more than there is a
25 presence of a delayed-release coating, because phthalate is the

1 component on hydroxypropyl methylcellulose that makes it a
2 delayed-release coating material.

3 Q Now, based on all the testing evidence that you've seen
4 from all the experts in the Impax case, what do you conclude?

5 A That Impax does not infringe the patent because it does not
6 have a stabilising coat deposited between the core element and
7 the delayed-release coat.

8 Q And what is your opinion as to whether testing of Impax's
9 unaltered product that has not been washed with 99 percent
10 acetone includes or shows the presence of the alleged
11 stabilising coat?

12 A None of the tests done on the unwashed pellets show a
13 second coat that would be considered the stabilising coat
14 according to the patent.

15 Q Could we go to Slide 16, please.

16 And here we've depicted a series of images that the
17 Court has already seen, and I don't want you to go into too
18 much detail here. But can you identify each one of these and
19 explain how it supports your conclusion?

20 A Scanning electron microscope done by Dr. Davies. He says
21 it's one layer. I agree;

22 Optical microscope done by that Dr. Davies. He says
23 single layer. I agree;

24 The work of Sodhi shows the distribution of talc in
25 the single layer, the work of Sommer shows -- and you've seen

1 this just a while ago -- this continuous layer, and of course
2 the second one over here is a continuous distribution of talc.
3 Every one of them shows a single layer with a uniform
4 distribution of ingredients that they identified using their
5 particular analytical technique.

6 Q And for the record, could you just read from the exhibit
7 numbers that you had referred to?

8 A Okay. So it's PTX 224 for the scanning electron
9 microscope; PTX 214 for the optical, ITX 396 for the EDS; ITX
10 432 for the ATR-FTIR; and ITX 219 for the T-o-F-S-I-M-S, or
11 ToF-SIMS.

12 Q And with respect to each one of these five different
13 methodologies that were used to analyze untreated, unwashed
14 crossed Impax seeds, did you see any evidence in court or in
15 the experts' reports or other evidence of this testing in this
16 case that you've reviewed, that is inconsistent with the
17 conclusions you drew based on these five specific images?

18 A None of these images are inconsistent with the conclusion I
19 drew based on reviewing all the data present.

20 Q And did you see any other instances of these five
21 methodologies that showed what you would view in your opinion
22 as establishing the presence of a separate coating between the
23 core and the enteric or the delayed-release coating of the
24 Impax product?

25 A No.

1 Q Okay. So let's move on from the presence of the stabilising
2 coat itself, your opinion that it's just not a coating. But do
3 you also have an opinion on whether what Dr. Davies alleges is
4 the stabilising coat, in fact, has been shown to function as
5 claimed, by keeping the migration of core materials to a
6 minimum such that the interaction of core materials with the
7 coating materials is reduced or prevented so that the
8 dissolution profile stability is established?

9 A No.

10 Q Have you seen any evidence that by its very presence the
11 alleged stabilising coat that Dr. Davies says was present must
12 function or does function to minimize migration of core
13 materials in Impax's product?

14 A No

15 Q Now, did you read Dr. Davies' testimony last week where in
16 his direct examination he pointed to a single question and
17 answer in one of your depositions and suggested that based on
18 that question and answer you had agreed that what Dr. Davies
19 characterized as a layer meets the minimizing migration
20 requirement -- let me --

21 MR. PACELLA: I apologize, your Honor. Let me start
22 over.

23 Q Did you read Dr. Davies' testimony where he pointed to a
24 paragraph in one of your declarations and he said that was a
25 recognition by you that by its very presence a layer of

1 materials will keep migration of core materials to a minimum?

2 A Yes, I did.

3 MR. PACELLA: And can we put up Impax Slide 29.

4 Q And this was from Dr. Davies' direct examination.

5 And is this the statement that you recall Dr. Davies
6 referred to and said that you were by this statement agreeing
7 that any material would necessarily, regardless -- without any
8 other information, would necessarily reduce migration to a
9 minimum?

10 A Yes. I think this is what he quoted.

11 Q All right. Does this statement indicate that you believe
12 that a material, no matter what it is, by its mere presence,
13 even if its unidentified in terms of its chemical structure or
14 formula, can function as a stabilising coat as required by the
15 claims?

16 A No. We were talking about the fact that the '777 Patent in
17 his examples uses identical material that is referred to in the
18 '161 Patent in the stabilising coat, and so that someone of
19 ordinary skill in the art reading that would say, well, if
20 they're using exactly the same material in the same way, it
21 should have the same effect.

22 Q And can one conclude that a material will function to keep
23 migration to a minimum as required by the claims without
24 knowing what that chemical compound is?

25 A I don't think so.

1 Q Have you ever agreed in this case that what Dr. Davies
2 characterized as a "layer" based on his acetone treatment
3 method meets the minimizing migration requirement of the
4 claims?

5 A I don't think so.

6 Q Okay. Did you also read where Dr. Davies pointed to one
7 question and answer from one of your depositions and he
8 characterized that answer as a recognition by you that the
9 patentees had seen that all you had to do to establish that,
10 whatever the stabilising layer allegedly is reduces migration,
11 is to do a dissolution stability study?

12 A I believe he referred to that, yeah.

13 Q And do you agree that because a product has dissolution
14 stability, then it therefore can be inferred that that product
15 has a stabilising coat that's functioning as required by the
16 claims?

17 A No, I don't.

18 Q Can you explain why not?

19 A The patent shows data to support its premise that the
20 inclusion of a stabilising coat will increase the stability of
21 the dissolution profile. And they do a comparative test
22 between a product with and without a stabilising coat. And
23 they infer from that, that the stabilising coat does indeed
24 improve the dissolution stability. And since they also say
25 that that is probably because it slows or prevents migration,

1 they conclude that it slows and prevents migration. That's
2 what the patentees say.

3 But there's no reason to think that a simple stable
4 dissolution profile automatically means there must be the
5 stabilising layer that the patent talks about in the product.

6 Q And in the context of the surrounding testimony, questions
7 and answers at your deposition in which that one question and
8 answer that Dr. Davies cited occurred, what were you
9 discussing?

10 A We were discussing how we would go about testing to see if
11 a coat placed between the delayed-release coat and the core
12 pellet could actually have an affect on dissolution stability.

13 Q And when you referred to the dissolution stability testing
14 that the patentees did, as I believe the question said, a
15 "surrogate" for reduction of migration, what were you referring
16 to?

17 A In the patent -- I think we could pull up an excerpt from
18 the patent.

19 But the patent has a comparative example and it
20 compares two different formulations, one with and without a
21 stabilising coat, and then it looks at the stability of that
22 formulation on a 24-minute dissolution time point over a
23 12-week period.

24 Q Okay.

25 MR. PACELLA: Could we go to PTX one, column 12, I

1 believe.

2 Q And this is drawn from column 12 of the '161 Patent.

3 Can you explain what's being shown here?

4 A Sure. What they did was on the column ahead of this they
5 actually made two different coded beads, one with a stabilising
6 coat and one without. And the one without a stabilising coat
7 they stored for various time, up to 12 weeks, and then they
8 looked at the release of the drug at 20 minutes, and it went
9 from 14 to 50. And then they said, well, let's look at the
10 impact of the stabilising coat. And when they put the
11 stabilising coat on, the percent released at 20 minutes went
12 from 6 to 20. So it was much more stable in terms of its
13 overall dissolution pattern.

14 Q Now, does that allow one to conclude that the stabilising
15 coat is, in fact, reducing -- is creating stability by
16 minimizing or reducing -- or keeping migration of components to
17 a minimum?

18 A This data shows that the stabilising coat used in this
19 example is indeed improving the stability of the
20 delayed-release coat. The supposition by the patentees is that
21 it reduces or impairs or blocks the migration of materials
22 between the core and the delayed-release coat.

23 Q Right. So can you infer that if the product is stable,
24 more stable with the stabilising coat than without the
25 stabilising coat, can you then infer that the stabilising coat

1 is, in fact, reducing migration or minimizing -- keeping
2 migration to a minimum?

3 A That's exactly what the patentees would suggest to you.

4 Q And for the record, we're looking at column 12, lines 20
5 through 30 of the PYX 1.

6 Did Dr. Davies provide any evidence to support the
7 proposition that, in fact, if a stabilising coat were not
8 present, core materials would migrate from the core in Impax's
9 delayed-release seeds?

10 A There was no testing by anyone of migration from the core
11 seed to the coat.

12 Q And can one infer that if a product has dissolution
13 stability, that the product then includes a stabilising coat
14 that's reducing migration?

15 A No.

16 Q Why not?

17 A Because there are lots of factors that could be changing
18 the stability of the dissolution pattern; including but not
19 limited to the environment in which it's packaged or stored,
20 and changes in other components of the material.

21 Q And can you give some samples of other changes in
22 components other than the dosage form that could impact
23 stability?

24 A Excuse me.

25 Q Do you have any examples of factors outside of the tablet

1 itself that can influence stability?

2 A I think I mentioned a couple of them already. One is that
3 you can control the moisture content of the container; you can
4 control the light that the active ingredient -- that the coat
5 is being exposed to; and you can control the temperature.

6 Q Okay. Have you seen any documents recognizing ways to
7 stabilize a product other than the dosage form itself?

8 A Yes.

9 MR. PACELLA: Can we look at some samples? Let's
10 start with ITX 683.

11 Q What is ITX 683?

12 A It's a report from Faulding that was published in -- or
13 released in June of 2001, and it's a Process Development
14 Report.

15 Q And do you understand that Faulding was a predecessor to
16 Plaintiff, Mayne Pharmaceuticals?

17 A Yes, I do.

18 MR. PACELLA: And what -- can you go to page 42 in
19 this document. We're looking at ITX 683-042.

20 Q Does this include information relevant to what you've just
21 been discussing?

22 A Yes. The authors of this report say that they draw out
23 any -- the postulate is that tableting excipients improve
24 pellet stability in one of two ways. And they talk about it
25 drawing out residual solvent or water and slowing any drug

1 migration which might lead to hydrolysis of the enteric
2 polymer. They prevent moisture from absorbed into the pellet,
3 again slowing migration of drug and hydrolysis.

4 So they changed the tablet excipients.

5 Q And so do either of those ways that the patentees -- or the
6 authors of this Process Development Report postulated stability
7 could -- or that slowing migration could occur involve using a
8 stabilising coat?

9 A No.

10 Q Let's take a look at ITX 680.

11 Do you recognize ITX 680?

12 A Yes.

13 Q What is ITX 680?

14 A It's a report from one of the inventors about the 75
15 milligram capsule, and it has on the bottom of it a desiccant
16 study for the 100 milligram induct-sealed bottles.

17 Q Okay. And this report is dated June 6, 2001?

18 A Yes, it is.

19 Q And Stefan Lukas is one of the inventors of the Patent, the
20 '161 Patent?

21 A That's what I said, yes.

22 Q I'm sorry, I misheard you.

23 What does this letter indicate about the relationship
24 between stability and factors other than the use of a
25 stabilising coat?

1 A It says that it's apparent, based on drug release and acid
2 at 20 minutes, that the addition of a desiccant sachet, either
3 one or two, significantly improves stability.

4 Q Now, is this document related to the -- it's related to
5 Doryx. Correct?

6 A Yes.

7 Q And do you know if this is the capsule or the tablet?

8 A I believe it's the 75 milligram -- the 100 milligram -- I
9 believe it's -- well it's confusing at times because it relates
10 to two or three different things as you read through the memo.

11 They talk about the 75 milligram capsule, they talk
12 about the 100 milligram Doryx in a sealed bottle, and on the
13 next page they talk about tablets and pellets in the final
14 formulation.

15 Q Now, have you seen any evidence that the Impax product
16 meets the stability requirements, the dissolution stability
17 requirements of the asserted claims without the use of its
18 packaging and the inclusion of that packaging of a desiccant?

19 A No.

20 MR. PACELLA: Okay. Let's take a look at ITX 681.

21 Q What is ITX 681?

22 A This is a memo to the Food and Drug Administration from
23 Warner Chilcot, and it talks about an amendment or supplement
24 to the Doryx capsule, 75 milligram, and it talks about the
25 addition of a desiccant package.

1 Q Okay. And what does it say about the addition of a
2 desiccant package?

3 A Okay. And I think there's a conclusion --

4 Q If you go to page 5.

5 A The conclusion is: Upon comparison of the data in Tables
6 1, 2 and 3, it can be concluded that the addition of a
7 desiccant appears to improve the stability of the tablets.

8 Q And if -- sorry.

9 A And what I think happened -- because if you look above,
10 we're talking about NDA 50-582 and doxycycline hyclate
11 delayed-release capsules, even though they say tablets down
12 here, I think that might be a typo.

13 Q Okay. But based on the "re" line of this document, it's an
14 amendment to supplement Doryx capsule 75 milligram NDA,
15 addition of a desiccant pack. Correct?

16 A That's correct.

17 Q And so in this document Warner Chilcot is asking the FDA to
18 approve an amendment to the NDA for the Doryx capsule by adding
19 a desiccant pack?

20 A That's what I think it means, yes.

21 Q And the Doryx capsule, is that the product that lacks a
22 stabilising coat?

23 A It's the prior art product, yes.

24 MR. SEPHTON: Objection. Lack of foundation for that
25 statement.

1 Q Have you reviewed documents relating to the --

2 THE COURT: Hold on, wait a second.

3 Overruled. Go ahead.

4 MR. PACELLA: I'll withdraw the question, your Honor.

5 Q Now, have you seen any evidence demonstrating that the
6 stability of Impax's tablet is in any way impacted by what Dr.
7 Davies calls a stabilising coat?

8 A No.

9 Q Do you know what makes Impax's tablet stable?

10 A Not exactly.

11 Q Well, how would one properly go about determining if
12 Impax's tablet was stabilized by one or more of the potential
13 factors that can lead to stability?

14 A You test tablets with and without a change in that factor.

15 Q And what factor -- for instance, if you wanted to know
16 whether Impax's tablet included a stabilising coat that
17 contributed to stability, what would be the appropriate
18 methodology?

19 A The best test would be to make the product with and without
20 the stabilising coat or the alleged stabilising coat, and see
21 if it actually does stabilize the product.

22 Q And if you wanted to know whether Impax's tablet was
23 stabilized by the desiccant, the use of a desiccant, what would
24 be the appropriate methodology to make that determination?

25 A You would take two bottles of the product, store one with a

1 desiccant, one without the desiccant and then measure the
2 stability of the dissolution profile at the time.

3 Q And have you seen any testing by Dr. Davies that explored
4 whether Impax's tablet would meet the claim dissolution
5 parameters of the asserted patent claims in the absence of the
6 desiccant that Impax uses?

7 A No.

8 Q Have you seen any evidence at all that that's the case?

9 A No.

10 MR. PACELLA: Could we go to ITX 678, please.

11 Q Dr. Kibbe, could you recognize ITX 678?

12 A Yes.

13 Q And this is a May 2008 Product Development Report?

14 A Yes, it is.

15 Q And you understand this to be an Impax --

16 A Yes, it is.

17 Q -- report?

18 MR. PACELLA: Could we go to page 25.

19 Does page 25 of Impax's -- this particular development
20 report discuss factors that might play a role in the stability
21 of Impax's product?

22 A Yes, it does. And let me just -- for everybody's ease,
23 there are three sets of numbers on these pages, okay? So the
24 Impax doc ends with 34225; the ITX number ends with 024.

25 MR. PACELLA: And for the record, just to be clear,

1 all the page fallouts, references to page numbers, your Honor,
2 have been to the lower right-hand corner that follows the
3 exhibit number.

4 THE COURT: All right.

5 A Okay.

6 Q Thank you, Dr. Kibbe.

7 A So the quote that I pulled out is: To improve dissolution
8 on stability -- which is the issue of the case -- the packaging
9 configuration was changed to use a molecular sieve desiccant
10 instead of a silica gel desiccant. As of this writing no
11 official data was available. However, unofficial data showed
12 improvement.

13 Q And how is that relevant to whether -- what factors
14 contribute to the stability of Impax's product?

15 A It's clear that if the data that they -- preliminary data,
16 the unofficial data is borne out with a full study, that the
17 shift from silica gel to a more efficient desiccant, molecular
18 sieve, does improve the stability.

19 Q Do you have a slide that would summarize the basis for your
20 opinion that there is no evidence that Dr. Davies' alleged
21 stabilising coat functions as required to keep migration to a
22 minimum that's required by the claim construction?

23 A I do. I do.

24 MR. PACELLA: Could we put up Slide 17, please.

25 Q Dr. Kibbe, could you please summarize your opinion as to

1 the functional aspect of the stabilising coat?

2 A Okay. So there's no evidence that the Impax tablet itself
3 provides the claimed dissolution stability. Even though you
4 can do a dissolution profile on it, we know that there are
5 other factors that might keep that profile stable;

6 Dr. Davies incorrectly assumes a stable product has a
7 stability coat when, of course, there are other factors that
8 could cause it to be stable;

9 There's no valid comparison of Impax's product
10 stability in the absence of packaging a desiccant, which are
11 not part of the product but rather part of the storage
12 situation.

13 Q Now, Dr. Kibbe we had a lot of information --

14 MR. PACELLA: I'm about to wrap up your Honor -- but
15 Dr. Kibbe has had a lot of information that he's presented, so
16 that I would like Dr. Kibbe to just summarize the essence of
17 all the opinions that you've reached in this case.

18 And if we could have Slide 18, please.

19 Q Dr. Kibbe, could you just summarize the basis for your
20 conclusion why Impax's product does not infringe?

21 A Okay. Impax's product does not infringe because there is
22 no stabilising coat. The manufacturing process applies a
23 single delayed-release layer. All the testing of an intact
24 seed shows a core with a single coating. The alleged
25 HPMCP-derived material is identified by the same phthalate

1 group that provides the delayed-release properties. There's no
2 evidence that Impax's modified release preparation provides the
3 required dissolution stability, and no evidence that the
4 alleged stabilising coat reduces migration or contributes to
5 stability.

6 MR. PACELLA: That's all I have, your Honor. Thank
7 you.

8 THE COURT: Thank you.

9 Cross-examination, please.

10 MR. PACELLA: Thank you, Dr. Kibbe.

11 MR. SEPHTON: I'm going to do the easy part, your
12 Honor. Because I'm going to be referring to some pictures I
13 thought you might want to have your own pointer just in case.

14 THE COURT: Oh. Thank you.

15 CROSS-EXAMINATION

16 BY MR. SEPHTON:

17 Q Good afternoon, Dr. Kibbe.

18 A Good afternoon.

19 Q I'd like to start off first with just discussing a claim
20 construction issue.

21 You are Mylan and Impax's claim construction expert in
22 this case. Correct?

23 A Yes.

24 Q And you submitted a declaration in 2010. Correct?

25 A Yes.

1 Q So what I'd like to do right now to start off is to talk
2 about what your understanding of an intermediary coating is.

3 A Okay.

4 Q Now, earlier on in this case you had tested some samples of
5 Warner Chilcot's Doryx tablet product. Right?

6 A Not exactly.

7 Q Well, sir, you commissioned some testing. Correct?

8 A Absolutely.

9 Q Okay. And that's the product for which the Impax and Mylan
10 want to make a generic copy of. Correct?

11 A Yes.

12 Q And you used SEM analysis in your testing?

13 A The individuals that I asked to do the testing, yes.

14 Q Okay. And they also did something called EDS?

15 A Yes.

16 Q And that's what Dr. Sommer talked about this morning?

17 A Yes.

18 Q Okay. And your testing, when you were looking at those
19 pellets, was to see whether or not there was an intermediary
20 layer in the samples, including the Doryx pellets that you
21 looked at. Correct?

22 A Yes.

23 Q Okay. And you determined from those tests that the Doryx
24 pellet had an intermediary layer that was distinct from the
25 core. Correct?

1 A The SEM seemed to show an intermediate layer in the Doryx
2 product but not in the Impax product.

3 Q And do you -- you concluded it was clear even to a lay
4 person that the Doryx product had a detectable intermediate
5 layer. Correct?

6 A Yes, I thought it was fairly obvious.

7 Q Okay.

8 MR. SEPHTON: Could we please put up Impax Doc 70100,
9 please.

10 Q And so, Dr. Kibbe, this is one of the Doryx pellets that
11 you had tested. Correct?

12 A Yes.

13 Q It's a SEM of a portion of the bisected pellet?

14 A Yes.

15 Q And you see the number right here at the bottom, it's a
16 long number, it's got a "dash 2"?

17 A Yes.

18 Q That's a serial number that identifies the Doryx tablet
19 pellet. Correct?

20 A Yes.

21 What happened was that I took the tablets from each of
22 the bottles that I obtained and I crushed them and removed
23 pellets from each one and labeled them in Vials 1, 2, 3, 4 and
24 5 and then sent them blinded to the doctor who ran this test
25 and just asked him to tell me what he thought was the structure

1 of the products. So he -- excuse me -- she didn't know what
2 product she was testing. And so she came back with these
3 reports where she said that there was an outside layer, which
4 she labeled with this red arrow, and she gave this EDS -- and
5 I'm blanking -- I'm sorry -- the EDS scan; then she said that
6 there's the second layer here, which is clearly laid out with a
7 very light color, and she gave it this scan; and then she said
8 this is the core with this scan.

9 When she did the same thing with the Impax tablet.

10 She only found the one delayed-release coat.

11 Q Sir, I just wanted to focus on the Doryx pellets.

12 A Fine.

13 Q Okay. And so you agree that that's the Doryx pellet
14 number. And she actually tested two of those pellets.

15 Correct?

16 A Yes.

17 Q Okay. And just going through, you had gone and identified
18 the outer coating layer which was identified as having a carbon
19 and oxygen-rich region. Correct?

20 A Yes.

21 Q And then the blue arrow is pointing to a white area that
22 was high in sodium and chloride?

23 A That's right.

24 Q Okay. And then the core region which was rich in carbon
25 and oxygen. Correct?

1 A That's right.

2 Q And she also has a scale bar up here which is 100 microns.
3 Correct?

4 A That's correct.

5 Q And so, you concluded that this region right here, this
6 white area, was a coating and that that would be an
7 intermediary layer coating that would be clear even to a lay.
8 Correct?

9 A I thought it was fairly obviously, yes.

10 Q Okay. Now, this is just a section, small section of the
11 bead. What I'd like to do is have the image we're looking at
12 right now just put up in the corner.

13 MR. SEPHTON: And could we put on, please, an image
14 from Bates number 70469.

15 MR. PACELLA: Your Honor, I object to this exhibit.
16 This is not on their exhibit list. We don't even know what it
17 is.

18 THE COURT: 7046 -- 04697? It's not on your exhibit
19 list?

20 MR. SEPHTON: Your Honor, actually this is just pages
21 from a document that Impax had on their exhibit list. I just
22 thought it would be simpler, more convenient to just deal with
23 what I wanted to talk about.

24 It comes from -- I'll tell you where it comes from.

25 (There is a pause for Mr. Sephton.)

1 MR. CONDE: PTX 300 and 301.

2 MR. SEPHTON: PTX 300 and 301.

3 THE COURT: All right.

4 BY MR. SEPHTON:

5 Q Okay. So, Dr. Kibbe, this is now an image of the entire
6 bead that we were looking at just now. Correct? And you can
7 tell that from looking at this region here matches with this
8 region here.

9 A This one right here is that? Is that what you're saying?

10 Q Right.

11 A Right, okay.

12 Q You agree with that?

13 A It looks like that's true.

14 Q Okay. All right. And now this is the image of the entire
15 bead, and you can see the layer goes all the way around the
16 bead that you identified, the intermediary layer?

17 A It appears to go around most of the bead. This report was
18 given to me, and of course the purpose of the report wasn't
19 necessarily to establish an intermediate bead but to get a
20 comparative between the Impax product and the Doryx product to
21 see if there was indeed a difference.

22 Q Okay. And just one last thing I would like to cover --

23 THE COURT: This is the Doryx bead. Correct?

24 THE WITNESS: Yes.

25 MR. SEPHTON: Actually I think you had asked during

1 the preliminary injunction hearing, your Honor. I thought you
2 would be interested in this image.

3 THE COURT: I asked during the trial, too, a few days
4 ago if anybody had done an analysis.

5 Is this the Doryx '161 Patent bead?

6 MR. SEPHTON: Yes, sir, it's the product covered by
7 the patent.

8 THE COURT: Okay.

9 BY MR. SEPHTON:

10 Q And Dr. Kibbe --

11 THE COURT: Let me back up again.

12 Doctor, did this witness do this analysis of this
13 bead?

14 MR. SEPHTON: Did Dr. Kibbe?

15 THE COURT: Yes.

16 MR. SEPHTON: Yes, he was responsible for the testing,
17 he supervised.

18 Q And you agree you supervised the testing, Dr. Kibbe?

19 A I prepared the samples and turned them over to the
20 spectroscopist who did the test. She worked for a company
21 called Schott Glass that makes glass images and glass lenses.

22 Q Okay. And just going back to this image, if you look
23 around the border you see that there's some regions here that.

24 Would you call those signs of cratering?

25 A Are you talking about here?

1 Q Well, not specifically there. Like right here, or down
2 here (indicating).

3 A I'm not sure. The whole purpose of the experiment was to
4 see if there was a difference between the commercial Doryx and
5 the Impax. And I think that was fairly well borne out by the
6 experiment.

7 I didn't use this to -- because I'm not a
8 spectroscopist, so that I didn't use this to support my opinion
9 that the Doryx manufacturing process only puts down one layer.
10 But she was blinded and her data was dead on each time. She
11 found two layers in the Doryx product and only one layer in the
12 Impax product, and that's what I was interested in.

13 Q And just for clarity of the record, she didn't treat any of
14 the samples she was looking at with any kind of solvent.
15 Correct?

16 A She didn't do anything to them.

17 Q One other thing, Dr. Kibbe, if you could just turn to your
18 book, it's PYX 1. I think you had testified that the '161
19 Patent does not concern bioavailability. And I just wanted to
20 make sure I understand what you're saying.

21 The concept of bioavailability includes in it the
22 concept of the ability of the drug to be absorbed in the body.
23 Is that correct?

24 A Yes, it does.

25 Q Okay. And so I just would like to direct your attention to

1 column 3 of the '161 Patent beginning at around line 38.

2 And you see there's a paragraph there, and about four
3 lines down it's talking about compounds that have a narrow
4 absorption window high in the gastrointestinal tract?

5 A Yes.

6 Q You see that?

7 So are the inventors here saying that the release
8 profiles that they're able to provide here are good for
9 compounds that have a narrow absorption window high in the
10 intestinal tract?

11 A They are saying that.

12 Q Okay. And so to the extent the patent talks about
13 absorption, the inventors were concerned about bioavailability,
14 wouldn't you say?

15 A I think they -- every formulator is concerned with that
16 when they begin the formulation development. But those
17 concerns had already been addressed in the prior art, and this
18 patent talks about stabilizing the dissolution pattern that
19 gives you these benefits.

20 Q Well, the inventors are saying here that certain
21 antibiotics have a narrow -- have a narrow --

22 (Mr. Sephton confers with Mr. Conde off the record.)

23 Q One other thing. If we can just go back, I realized I
24 skipped over something in the last slide.

25 Just so that it's clear on the record, I think it's

1 clear in the image here. Is this a gap here, sir?

2 We're now looking at 70469, and I'm looking at around
3 4 o'clock.

4 A Right here?

5 Q Yes.

6 A That's probably a gap in the sodium chloride but not
7 necessarily a gap in the intermediate coating layer.

8 Q And do you see other gaps up here?

9 A Yes.

10 Q All right. Do you see gaps all the way along with the
11 white area. Correct?

12 A Right. Right. There's no claim -- I think that what we're
13 making is a sodium chloride-enriched intermediate layer. We're
14 just saying that there's an intermediate layer and you can see
15 it on the SEM, and that's all.

16 Q Sir, just to be clear. You said it was clear even to a lay
17 person that this picture showed the presence of an intermediary
18 layer. Correct?

19 A That's right.

20 Q Okay. while we're in the patent, sir, I would just like to
21 direct your attention to column 6, around line 45.

22 And just around line -- actually, say, 49, the
23 patentees state that for their invention: Any active
24 ingredient that causes nausea or irritation but also has a
25 narrow absorption window high in the intestines will benefit

1 from the application of this invention.

2 A Yes.

3 Q So that's another example of the inventors talking about
4 the concept of bioavailability in their patent?

5 A They are concerned with side effect profiles and
6 availability, but the claims deal with stabilising something
7 that's already been developed.

8 Q Okay. Now let's talk for a moment about dissolution
9 profile.

10 A Sure.

11 Q In your opinion, a single time point is not a dissolution
12 profile. Is that correct?

13 A A profile is a continuous line that covers the dissolution
14 of a product over a period of time.

15 Q Okay. And so that you would have a number of time points?

16 A Probably.

17 Q Okay. Certainly more than one?

18 A Yes.

19 Q Okay. And the claims require multiple time points,
20 correct, claims of the '161 Patent and a dissolution profiles
21 when they refer to dissolution profile?

22 A They require a stability in the dissolution profile.

23 Q Right. And to do that dissolution profile you have to have
24 a number of dissolution points?

25 A Yes.

1 Q Okay. Let's just touch for a moment on your report for
2 non-infringement, Dr. Kibbe. That's dated August 19th, 2011.

3 If you don't have the date in mind, it should be near
4 the beginning of your binder, the last page, page 34.

5 Correct?

6 A I'm sorry. This isn't it then.

7 Q Oh, you have another binder --

8 MR. CONDE: He has the deposition binder.

9 THE WITNESS: I have four binders. I just want to
10 know which one.

11 MR. SEPHTON: May I approach, your Honor?

12 THE WITNESS: Yes, please.

13 THE COURT: Sure.

14 THE WITNESS: Which one are you talking about?

15 MR. SEPHTON: Let's see. This one.

16 THE WITNESS: Oh.

17 BY MR. SEPHTON:

18 Q The black one?

19 A Oh. I thought --

20 Q All right.

21 A I thought you were going to a separate document. I'm
22 sorry.

23 Q I apologize for the confusion, Dr. Kibbe.

24 A Okay.

25 MR. SEPHTON: And, your Honor.

1 A It's ITX what?

2 Q It's not ITX. It's your report, it's either the third tab
3 in second or third tab in.

4 A Okay.

5 I think I have it.

6 Q Okay. And August 18th, that's of last year, that's when
7 you signed your report?

8 A Okay. Yes, I have it.

9 Q Okay. And you commented in your report on the results of
10 Dr. Sohdi and Sommer's testing?

11 A Yes, I did.

12 Q And you have it in several paragraphs in your report?

13 A Yes, I do.

14 Q And you did not review Dr. Sommer or Sohdi's reports until
15 after they had been finalized and signed. Correct?

16 A I reviewed them when they were finalized and signed, yes.

17 Q And you never saw a draft report of either. Correct?

18 A I didn't see a preliminary draft report, no.

19 Q Okay. Do you know that Drs. Sohdi and Sommer also signed
20 their reports also on August 18th, 2011?

21 A No, I thought that I had gotten a complete report before
22 that.

23 Q Well, sir, do you recall when I asked you at your
24 deposition whether you had seen either of their reports before
25 you signed yours, you said that you had never gotten them

1 before they were finalized?

2 A Well, I thought they were finalized when I read them,
3 that's why I said that.

4 Q Well, sir, I think you said the signed, dated document is
5 what you saw. Do you recall that?

6 A That's what I said, yes. But that's when I thought I saw
7 them.

8 Q Okay. So just to be clear, your testimony is, you did not
9 see Dr. Sohdi's or Sommer's reports before you saw their signed
10 finalized reports. Correct?

11 A Well, at the time I thought that I had seen their signed or
12 final report before I completed my report, yes. And if they
13 weren't the signed reports, I apologize, but that's what I
14 thought I had seen.

15 Q All right. Sir, I would have to take you to your
16 deposition. It's the one from December 4th of this year. And
17 go to page 2238.

18 A Okay. Can you help with which one of these?

19 Q There should be date marks, there should be a date in front
20 of it.

21 MR. SEPHTON: May I approach, your Honor?

22 A I don't see a date on the front, but that's okay. This one
23 is April 22nd.

24 Q That isn't it.

25 They didn't put a date on the front?

1 A No, that's why I asked.

2 Q So it will be this one.

3 A Are you sure?

4 Q Yes, I'm sure.

5 A Okay. So you're telling me that the undated one is the
6 April 4th one?

7 Q No, I'm not saying that.

8 Sir, if you could go to page 238 around line 9, I
9 asked a question:

10 (Reading) And did you review their reports, either of
11 their reports in the month of September?

12 There's an objection.

13 "ANSWER: I will tell you, I don't remember exactly
14 when I reviewed anything. But whenever they were submitted,
15 then sometime after that I got them. I never got them before
16 they were finalized. I didn't look at an intermediate report
17 or do that.

18 "QUESTION: How do you know that?

19 "ANSWER: Because the document I got was signed and
20 dated.

21 "QUESTION: The document you got -- what you reviewed,
22 The only Sodhi report you looked at was a signed, dated
23 document of his report?

24 "ANSWER: That's what I remember.

25 "QUESTION: Okay. The same for Dr. Sommer?

1 "ANSWER: Yes."

2 Did I read that --

3 MR. PACELLA: Your Honor, I believe that is exactly
4 what the witness just said in his testimony. I would have
5 objected earlier, but we do object to this bringing out the
6 deposition transcripts with totally consistent statements.

7 THE COURT: All right. Your objection is overruled.
8 Go ahead.

9 Q Did I read that correctly?

10 A You did.

11 Q Just a brief moment on Impax's products.

12 You were discussing I think in your binder -- Dr.
13 Kibbe, if you go to ITX 621.

14 A Okay.

15 MR. SEPHTON: And hopefully we won't have to seal the
16 for the record for this, but just in case.

17 ***** (THE RECORD IS SEALED) *****

18 Q If you look on that page, under "delayed-release coating,"
19 you see there's a hypromellose phthalate indicated there?

20 A Yes.

21 Q Okay. And then below that is the hypromellose. That's
22 HPMC?

23 A Yes.

24 Q And the HPMC is in an amount ten times less than the HP-50.
25 Correct?

1 A Yes.

2 Q And in terms of the percent of HP-50 in Impax's
3 delayed-release coating, it's on the order of 58 percent.
4 Correct?

5 A 58 percent of?

6 Q Of what's put in the coating, the salt materials.

7 A The coating itself?

8 Q Yes, sir.

9 MR. PACELLA: Your Honor, could I ask the have to
10 record sealed if we're going to be talking about specific
11 percentages of ingredients.

12 THE COURT: All right. Mr. Perelli, would you please
13 seal it from this moment on.

14 And please indicate afterwards when you want it
15 unsealed. Thank you.

16 A That's an approximate -- I could do the calculation if you
17 like, but --

18 Q Okay. And I think we can probably seal it back up.

19 ***** (THE RECORD IS UNSEALED) *****

20 Just one more thing. The bottom of that page shows a
21 tablet weight for this product. Do you see it's over 900
22 grams?

23 A It's not grams, milligrams.

24 Q Sorry, I beg your pardon. You're right, that would be too
25 big. So almost a gram?

1 A 900 grams, we have elephant products then.

2 Q Yeah.

3 A Right. Then this is close to a gram. Right?

4 Q And one gram is about the upper limit for tablet size,
5 would you say?

6 A We try to keep our tablets under a gram to make them easy
7 to swallow.

8 Q So is it fair to say that it's the upper limit, sir?

9 A It's close to the upper limit. There are tablets that are
10 out there that weigh more than that because they are more dense
11 than the average tablet. But this is a common rule, try to
12 keep the tablet under one gram.

13 Q Generally accepted --

14 A Yes.

15 Q -- that that's the upper limit?

16 A Yes.

17 Q And I think, I just want to be clear on your testimony
18 today, you're agreeing that you did not expect any of the
19 components in Impax's delayed-release core to interact with its
20 delayed-release coating?

21 A Yes, I agree with Dr. Davies on that, I wouldn't expect an
22 API.

23 Q Just so we're really clear, you do not expect the active
24 pharmaceutical ingredient to interact with the delayed-release
25 coating in Impax's product?

1 A No, I didn't.

2 Q Okay. Turning a moment to acetone washing -- but
3 before we do that, Dr. Kibbe, you did not do any searches to
4 see where others had removed coatings on a pharmaceutical using
5 a solvent. Correct?

6 A No, I didn't.

7 Q Okay. And before this case, you had never been aware that
8 people had removed a coating on a pharmaceutical product using
9 a solvent. Correct?

10 A No. I'm sure that there were times when people removed a
11 coating in order to determine the weight or size of the
12 coating, but never to remove it to hunt for a coating
13 underneath it.

14 Q Can you go to page 108 of your deposition, please, sir.

15 A Okay. Which one now?

16 Q The same book that we were in last time.

17 A 108?

18 Q 108.

19 A Okay.

20 Q So beginning at line 8 there I asked the question:

21 (Reading) Well, have you -- aside from that limited
22 purpose, have you ever heard of people removing coatings using
23 organic solvents, regardless of their purpose?

24 "ANSWER: It's just clearly something I -- I haven't
25 heard of in general, no."

1 Did I read that correctly?

2 A Yes, you did.

3 Q You were asked those questions and you gave those answers?

4 A Yes, I did. And if -- well...

5 Q So in terms of acetone washing, your position is that 99/1
6 acetone/water mixture would not dissolve Impax's
7 delayed-release coating. Have I got that right?

8 A Yeah. I don't think that would be a good choice, no.

9 Q Okay.

10 I'm not sure if you understood my question, sir.

11 Your position is that 99/1 acetone/water -- not is it
12 just not a good choice -- you're saying it would not dissolve
13 any part of Impax's delayed-release coating?

14 A I didn't say that.

15 Q All right. That would be wrong? You're saying it would?

16 A Okay, let's try to be careful.

17 You said "not any part." And I said I didn't say
18 that.

19 It would dissolve some of it away, but I said it was a
20 poor choice to do the study that Dr. Davies was attempting to
21 do, which was to wash away the entire coat.

22 Q In fact, so you agree that Dr. Davies' acetone/water
23 treatment extensively removed Impax's delayed-release layer?

24 A You're putting modifiers in what I said.

25 Q All right. Extensively changed the layer?

1 A It changed the layer. It could very well have dissolved
2 away the triethyl citrate which is freely soluble in acetone,
3 it might have dissolved away different portions of the other
4 ingredients, yes.

5 Q Sir, it reduced the size of the coating. Correct?

6 A It certainly would have.

7 Q And your position is that Dr. Davies, if he had rinsed long
8 enough, it would have dissolved the whole thing. Right?

9 A My position is that he didn't dissolve the whole thing, and
10 what was left behind was not a suddenly appearing new coat that
11 no one saw before, but was the residual of what he didn't
12 finally wash off.

13 Q Let's go to storage stability testing, Dr. Kibbe.

14 When one is doing FDA storage stability testing, the
15 product is going to be in its bottle that you're going to sell
16 the product in. Is that right?

17 A Yes, that's right.

18 Q Okay. And if there's any desiccant pack or cotton batting,
19 the FDA expects you to run a test with that in the bottle as
20 well?

21 A Right. They want you to verify that the product you intend
22 to ship and market is stable.

23 Q All right. And so you understand that in the '161 Patent,
24 column 2, they provide instruction that the testing -- the
25 post-storage dissolution testing is supposed to be done

1 according to the FDA and in its container and package?

2 A It provides testing that should be done to make sure that
3 you've carried out the properties of the product in an FDA type
4 testing situation, yes.

5 Q And, in fact, they say that it should be carried out on
6 preparations subject to a standardized storage test based on
7 accelerated conditions of storage referred to in the United
8 States Food and Drug Administration, FDA guidelines. The
9 guidelines define "accelerated conditions," and then they give
10 those conditions, and they indicate that it's going to be in
11 its container and package. Correct?

12 A That's correct. That's right, those are ICM guidelines.

13 Q And the package would include the plastic bottle. Right?

14 A It includes everything.

15 Q If there's a desiccant it would include that as well?

16 A It certainly would.

17 MR. SEPHTON: And this is the last thing, your Honor.

18 THE COURT: That's fine. Go ahead.

19 BY MR. SEPHTON:

20 Q If we could just turn back to your report, Dr. Kibbe.

21 A Okay.

22 Q Maybe if we could put up on the screen. It's going to be
23 the table on page 28 of Dr. Kibbe's report.

24 This is the portion of your report where you were
25 talking about a desiccant study that Impax had done, and I just

1 want to focus us for our discussion on the 30-count bottle
2 data. Okay?

3 And so --

4 A For both 75 and 100 or just 75?

5 Q I'll walk through them, sir.

6 A Okay, good.

7 Q So for the 75, for the 30 bottle, with one desiccant that
8 Impax had, the -initial dissolution was 39, and it went up 10
9 points after 13 weeks. Correct?

10 A Yes, it did.

11 Q Okay. And the 100 milligram bottle went up 9 points during
12 the same time frame having the same desiccant. Correct?

13 A Yes, that's the silica gel Minipax, right.

14 Q So the delta for both of those was 9. Correct? For 9 or
15 10?

16 A Thank you. 9 or 10.

17 Q Okay. Now, you had referred to a study in ITX 678, and I
18 think you had been taken to the page that's ITX 678-024.

19 And you don't need to go there, sir, but do you recall
20 that testimony? You referred to the desiccant study that Impax
21 had run.

22 A Yes, I remember.

23 Q And we were looking at the results of the desiccant study.
24 Right?

25 A I think so.

1 Q And Impax concluded that they switched one desiccant for
2 another because they thought another one was better. Right?

3 A Yes.

4 Q Okay. So now let's go to page 29, the table at the top.
5 And this is now the dissolution data with the new desiccant
6 that Impax switched to. Correct?

7 A Yes.

8 Q Okay. And look at the 30-count bottle. Do you see the
9 delta went from 43 to 34. Right?

10 A That's right.

11 Q And so the delta there was almost the same as the other
12 deltas we were looking at with the previous desiccant.
13 Correct?

14 A That's.

15 MR. SEPHTON: I have no further questions, your Honor.

16 THE COURT: Thank you very much.

17 Any redirect?

18 MR. PACELLA: Briefly, your Honor.

19 THE COURT: Sure.

20 MR. PACELLA: May I proceed?

21 THE COURT: Yes, you may.

22 REDIRECT EXAMINATION

23 BY MR. PACELLA:

24 Q Dr. Kibbe, I just had a couple follow-ups.

25 In your deposition transcript, Plaintiffs pointed to

1 one question and answer. And I believe we can go to page 108,
2 they cited this sentence that said:

3 Well, the question was -- I want to make sure I get
4 this right.

5 I believe the question was:

6 (Reading) Have you heard of it specifically?

7 And we were talking about whether you had seen
8 references in the past of using an acetone or some kind of
9 solvent wash in order to remove a coating.

10 And your answer was:

11 The suggestion was that --

12 MR. SEPHTON: Your Honor, this is improper use of
13 deposition transcript.

14 MR. PACELLA: Well, I don't have an exact --

15 THE COURT: Go ahead, let me hear the question first.

16 MR. PACELLA: Your Honor, there were some questions in
17 the context of Dr. Kibbe making an admission that people
18 removed coatings using organic solvents, and I believe the
19 question was: (Reading) Well, have you -- aside from that
20 limited purpose, have you ever heard of people removing
21 coatings using organic solvents, regardless of their purpose?

22 And the answer was: It's clearly something that I
23 have not heard of in general, no.

24 Well, have you heard of it specifically?

25 And it goes on.

1 BY MR. PACELLA:

2 Q But to put it into context, I just tell wanted to read a
3 portion where he was asked to go to his rebuttal report, and
4 the question was:

5 (Reading) Have you ever removed a coating on a
6 pharmaceutical product using organic solvents?

7 And the answer was "I don't think so."

8 Do you recall that, Dr. Kibbe?

9 A Yes, I do.

10 Q Then the question was: Have you also out of this case ever
11 become aware that people have done that in pharmaceutical
12 science?

13 And your answer was: Not in order to establish the
14 existence of another coat underneath, no.

15 Then the question was: Okay. Well, have you aside
16 from if limited purpose, have you ever heard of people removing
17 coatings using organic solvents regardless, of their purpose?

18 And the answer was: It's clearly something -- I
19 haven't heard of it in general no.

20 Have you heard of it specifically?

21 And then you said: I think there's a reference in one
22 of those tons of stuff I've read that talk about removing a
23 coat so that you can get an estimate of the weight of the coat
24 relative to the weight of the total product.

25 Was that your testimony?

1 A Yes, it was.

2 Q Was about the full context of the testimony surrounding
3 that question that the Plaintiffs counsel asked you?

4 A Yes, I think it was.

5 THE COURT: All right. I'll allow it. Go ahead.

6 MR. PACELLA: I just had one more thing, your Honor.

7 Can we pull up --

8 Q I don't have exhibits, but I believe Plaintiffs had put an
9 image that you had done commissioned some testing of a Doryx
10 tablet --

11 A Yes.

12 Q -- and they showed this image here. Is that correct?

13 A I believe so.

14 Q And this is from PTX 300.

15 A That's right.

16 Q And PTX 300, did they show the entire testing that was done
17 in connection with the experiment that you commissioned?

18 A No, they only showed one slide of one bead from a Doryx
19 product.

20 Q And did they show any of the results of what the SEM looked
21 like in the hands of this scientist who create this, or who
22 generated this image of what the Impax seed looked like?

23 A No, they didn't. There were three -- should be at least
24 three SEMs of that.

25 BY MR. PACELLA: Could we go to IMP DOC 71 70102. I'm

1 not sure it's in the -- I'm not sure it's in the PTX.

2 Can I use the ELMO?

3 Sorry, your Honor. The whole exhibit, the whole
4 report was not as the exhibit, so I'm trying to piece it
5 together.

6 Q Now, Dr. Kibbe, is this another one of the images that was
7 done in connection with the study that's reflected on that one
8 image from PTX 300?

9 A Yes.

10 Q And is this one on the right one of the Impax tablets?

11 A Yes, and I believe that the code number would be on the
12 back and would verify that.

13 Q And do you see anything in the --

14 MR. PACELLA: Can you blow that up? Blow them both
15 upside by side.

16 Q Do you see -- can you show the Court where you see the
17 sub-coating or the stabilising coat in the one on the left?
18 And if you see one on the right, can you show where that one
19 is?

20 A Okay. So what Dr. Gober-Mayer did is she identified the
21 region between here and there as an additional coat, and that's
22 where the arrow goes and it kind of runs along here. Some of
23 this is a result of the slicing technique she used because she
24 was not as sophisticated as either Sohdi or Sommer or Dr.
25 Davies in cutting the thing, and this was a preliminary look

1 that I asked her to do just to get a sense of a positive
2 control, meaning, I knew that one of them had a sub-coat, one
3 didn't, let's see what that looks like.

4 So it's not -- this is not the kind of data that I
5 would rely on like Dr. Sommer and Dr. Sohdi did.

6 And then looking at the other one and you can see that
7 clearly we have a coating layer that runs along in here, and
8 this is the core.

9 Q Do you see anything outside -- so can you point to where
10 the coating is?

11 A The coating layer is running right in through here.

12 Q And is there any second coating in there?

13 A There's nothing visible at all in there that would relate
14 to a second coating.

15 And when she did her analysis she only looked at one
16 point within each area for the spectrograph.

17 Q Can you go back -- just the last image for one more minute.
18 Now we're again look at the Doryx sample. We were just looking
19 at the Impax sample.

20 Can you point to where the -- there's a separation of
21 layers --

22 A So there's the -- what an I think would be the
23 delayed-release coat, and this would be the intermediate coat
24 and this would be the core.

25 MR. PACELLA: No further questions, your Honor.

1 THE COURT: Okay. Thank you.

2 Anything else?

3 MR. SEPHTON: No, your Honor.

4 THE COURT: All right. Doctor, you can step down.
5 Thank you very much.

6 THE WITNESS: Thank you.

7 (Witness excused.)

8 THE COURT: Who's got the next witness, Mr. Weisblatt?

9 MR. WEISBLATT: Yes, your Honor. Impax calls --

10 THE COURT: Wait. Is this still on infringement?

11 MR. WEISBLATT: No, this is not on infringement.

12 THE COURT: You're going to be calling -- what's his
13 name?

14 MR. WEISBLATT: It's a woman, your Honor, Dr. Tina
15 deVries. I hope I'm pronouncing that correctly.

16 THE COURT: What will she be testifying to, just
17 generally?

18 MR. WEISBLATT: She works at Warner Chilcot and she's
19 going to be testifying to some of the matters that were not
20 only raised by Dr. Davies on his direct examination but other
21 details of the development of the capsule and the
22 development -- particularly the development of the tablet.

23 THE COURT: Are we getting into the area of
24 invalidity, is that it?

25 MR. WEISBLATT: Yes, your Honor. Almost all of her

1 testimony will be relative --

2 THE COURT: So with respect to the issue of
3 infringement, pretty much all the evidence is in?

4 MR. WEISBLATT: All the evidence is in for Impax, your
5 Honor.

6 THE COURT: And for Mylan as well?

7 MR. SHATZER: On infringement, it is, your Honor.

8 THE COURT: All right. And for Warner?

9 MR. CONDE: Yes.

10 THE COURT: I just wanted to see.

11 Why don't we take a break and we'll resume at three
12 o'clock. Okay?

13 MR. SHATZER: Yes, your Honor.

14 THE COURT: Thanks.

15 MR. WEISBLATT: Your Honor, do you have any idea of
16 how long you're going to go today?

17 THE COURT: I don't know. At least until four, 4:15,
18 maybe more. We'll see. But we're okay I think.

19 How many more witnesses do we have total?

20 MR. WEISBLATT: Your Honor, there are, including Dr.
21 deVries, we have Dr. Kibbe will retake the stand about
22 validity, then we have Dr. McGinity who's the Plaintiffs'
23 expert on invalidity, and that's all we have left.

24 THE COURT: That's it?

25 MR. CONDE: That's it, that's right, your Honor.

1 I think we would like to finish Ms. deVries up tonight
2 since she is a fact witness who has come in from work in order
3 to make herself available for Impax.

4 THE COURT: Hopefully it won't be too long, we'll see.
5 We'll start at 3 o'clock. We'll try our best.

6 MR. CONDE: Thank you, your Honor.

7 MR. WEISBLATT: Thank you.

8 (A recess is taken.)

9 (Proceedings resume.)

10 THE DEPUTY CLERK: Please remain seated.

11 THE COURT: Go ahead, Mr. Weisblatt.

12 THE DEPUTY CLERK: Do you want call your witness?

13 MR. WEISBLATT: Yes. Impax calls Dr. deVries. And if
14 I mispronounce that, I apologize.

15 THE WITNESS: That's fine.

16

17 T I N A d e V R I E S called as a witness, having been first
18 duly sworn, is examined and testifies as follows:

19

20 THE DEPUTY CLERK: Please state and spell your name
21 for the record.

22 THE WITNESS: Tina deVries, d-e-V-r-i-e-s.

23 THE DEPUTY CLERK: Thank you. You may be seated.

24 MR. WEISBLATT: May I approach the witness, your
25 Honor?

1 THE COURT: Yes, go ahead.

2 DIRECT EXAMINATION

3 BY MR. WEISBLATT:

4 Q Dr. deVries, you've worked at Warner Chilcot since 1996.
5 Correct?

6 A Yes.

7 Q And when you joined Warner Chilcot you were responsible for
8 drug product development?

9 A Yes, that was one of my responsibilities.

10 Q And in 1999 you were the Senior Director of Research and
11 Development. Correct?

12 A Yes, I believe that was my title.

13 Q Do you recall when, Dr. deVries, you became the Senior
14 Director of Research and Development?

15 A I think it was in '96. I don't remember exactly when.

16 Q Certainly.

17 And in 2000 you became the Vice President of
18 Pharmaceuticals. Correct?

19 A Yes.

20 Q And you held that title until late 2005?

21 A I'm sorry?

22 Q You held that title of Vice President of Pharmaceuticals
23 until some time in 2005?

24 A Yes.

25 Q And in 2005 you became the Vice President of Clinical

1 Pharmacology at Warner Chilcot?

2 A Yes.

3 Q Is that still your position today?

4 A Yes.

5 Q Now, during your time at Warner Chilcot, one of the
6 products you were involved with was the Doryx delayed-release
7 tablet. Correct?

8 A Yes.

9 Q And, in fact, you were the person from Warner Chilcot
10 responsible for working with Faulding on the Doryx tablet
11 project. Right?

12 A Yes, I was a primary scientific contact with Faulding.

13 Q And, in fact, you were the person from Warner Chilcot who
14 actually oversaw the programs of the Doryx delayed-release
15 tablet project. Right?

16 A Yes, I was overseeing the progress and making sure they
17 were meeting the time line.

18 Q Now, was Faulding is known as Mayne Pharma, one of the
19 Plaintiffs in this case?

20 A They at one time were acquired by Mayne, I don't know what
21 their official name is today.

22 Q Okay. Did you ever know what the official name of Faulding
23 became?

24 A I didn't really pay attention to the official names.

25 Q Okay. Now, at Warner Chilcot for the Doryx tablet project,

1 you were responsible for research and development at Warner
2 Chilcot, were you not?

3 A I'm sorry. Can you repeat that?

4 Q Yes. At Warner Chilcot, you were the person who was
5 responsible for overseeing the research and development project
6 of the Doryx delayed-release tablet. Right?

7 A Yes.

8 Q And you were responsible for talking with Faulding about
9 the Doryx delayed-release project -- delayed-release tablet
10 project and for providing Warner Chilcot's comments and
11 feedback to Faulding. Correct?

12 A I -- I was responsible for overseeing the Faulding's
13 progress on the project from a scientific perspective.

14 Q Were you responsible for providing Warner Chilcot's
15 comments and feedback to Faulding during the Doryx tablet
16 project?

17 A I mean, I reviewed, you know, their progress on the project
18 and commented on it.

19 Q In essence, Dr. deVries, were you in charge of overseeing
20 the progress of the Doryx delayed-release tablet project for
21 Warner Chilcot?

22 A Yes.

23 Q Now, given that responsibility, you frequently received
24 documents such as progress reports and meeting minutes that
25 related to the Doryx tablet project. Right?

1 A I periodically received progress reports from Faulding on
2 the project.

3 Q Did you also receive documents that were internal to Warner
4 Chilcot about the Doryx delayed-release tablet project?

5 A Yes.

6 Q And you participated in meetings with Faulding and internal
7 meeting at Warner Chilcot that discussed the Doryx
8 delayed-release tablet project. Right?

9 A Yes.

10 Q Now, when you joined Warner Chilcot in 1996, Warner Chilcot
11 was selling Doryx delayed-release capsules. Correct?

12 A No.

13 Q That's not correct?

14 A My understanding is Warner Chilcot wall not selling Doryx
15 capsules when I joined in '96.

16 Q I wonder -- do you have a copy of your deposition, Dr.
17 degrees? It's this little binder.

18 A Okay.

19 Q If you would turn to page 27?

20 A Which numbers are you reading?

21 Q Page 27. And I don't know if you have -- it's -- I think
22 you might have a multi-page one?

23 A The little numbers in the right corner?

24 Q Yes, up at the top right of the document.

25 A Yes.

1 Q If you go to page 27.

2 A Okay.

3 Q And the lines are also numbered, Dr. degrees, on the
4 left-hand side of each page.

5 A Okay.

6 Q If you go to line 19 you were asked at your deposition:

7 (Reading) Was it on the market when you arrived, do
8 you recall?

9 And the answer you gave at your deposition was:

10 My understanding is that Doryx capsules were on the
11 market in 1996.

12 Right?

13 A That's what it says here, yeah.

14 THE COURT: Does that refresh your recollection as to
15 whether they were on the market then or not?

16 THE WITNESS: But I don't believe we were marketing
17 them.

18 THE COURT: Oh.

19 THE WITNESS: My understanding is that Parke-Davis was
20 marketing them at that time.

21 THE COURT: All right. Thank you.

22 BY MR. WEISBLATT:

23 Q Now, today, delayed-release Doryx capsules are not sold in
24 the United States, are they?

25 A I don't think so.

1 Q Do you know, are delayed-release Doryx capsules sold
2 anywhere in the world by anyone?

3 A I don't know.

4 Q So you don't have any information whether or not they were
5 sold in Australia?

6 A I don't know.

7 Q While Warner Chilcot -- or while Parke-Davis was selling
8 delayed-release Doryx capsules in the United States, Warner
9 Chilcot asked Faulding to develop the delayed-release Doryx
10 tablets for sale in the United States. Right?

11 A No, I don't understand -- no.

12 Q While the Doryx delayed-release capsules were on the market
13 in the United States, Warner Chilcot asked Faulding to develop
14 Doryx delayed-release tablets. Right?

15 A Okay. I'm a little bit confused.

16 Q Sure.

17 A Because you said that while they were on the market with
18 Parke-Davis?

19 Q Yes, then I changed my question to make it broader.

20 A Okay.

21 Q So I'll restate it again.

22 A Okay. Thank you.

23 Q While the Doryx delayed-release capsules were on the market
24 in the United States, Warner Chilcot asked Faulding to develop
25 a Doryx delayed-release tablet. Right?

1 A Yes.

2 Q Okay. Now, there are differences in the delayed-release
3 Doryx tablets and the delayed-release Doryx capsules. Right?

4 A Yes.

5 Q One obvious difference is one is a tablet and one is a
6 capsule. Correct?

7 A Yes, and the pellets are different.

8 Q Now, do you know of any specific differences between the
9 formulation of the Doryx tablet and the discontinued Doryx
10 capsule?

11 A You know, the biggest difference apart from the dosage form
12 is that the pellets are totally different. I mean, they're
13 both delayed-release pellets, but there's many differences
14 between the -- the pellets and the capsule and then the tablet.

15 Q So in terms of the capsule and tablet Doryx formulations,
16 is there any difference between them apart from one being a
17 capsule and one being a tablet?

18 A Yes.

19 Q What are those differences, as you understand them?

20 A Well, the pellets in the tablet are more stable in the acid
21 dissolution test. The drug-loading in the tablet pellet is
22 much higher than the capsule pellet. The tablet pellets are
23 much smaller than the capsule pellets.

24 Q Now, Doryx was the brand name for a line of products that
25 contained the active ingredient doxycycline hyclate?

1 A Yes.

2 Q Doryx was the brand name for delayed-release capsules and
3 it's now the brand name used for delayed-release tablets that
4 replaced the capsules. Right?

5 A Yes.

6 Q Now, the delayed-release capsule that was on the U.S.
7 market when you joined Warner Chilcot consisted of a capsule
8 shell filled with many small pellets that contained certain
9 amount of doxycycline hyclate as the active ingredient. Right?

10 A Yes.

11 MR. WEISBLATT: Could we show Slide 21.

12 Q Dr. deVries, is that an accurate depiction of the
13 doxycycline hyclate delayed-release seed that was in the
14 capsule?

15 A I'm not sure how specific it is, but it looks to be
16 generally accurate.

17 Q Now, the function of the delayed-release coating of the
18 capsule is to delay the release of the active ingredient while
19 the tablet resided in a patient's stomach, and accelerate its
20 release when it arrived in the small intestine. Right?

21 A No, I'm not quite following that.

22 Q Yes. I'm trying to get to the function of the -- what in
23 the picture is called the modified release coating, which I'm
24 also going to refer to as the delayed-release coating.

25 The function of that coating in the Doryx capsule is

1 to delay the release of the active doxycycline hyclate drug
2 while the pill is in the patient's stomach, and accelerate the
3 release of that drug when it arrives in the small intestine.
4 Right?

5 A That's not how I understand it.

6 Q Okay. The reason that the old Doryx capsule had a
7 delayed-release coating, wasn't it because immediate release
8 doxycycline hyclate caused irritation, nausea, stomach upset
9 and vomiting when it was released in the stomach?

10 A No. I did not develop the Doryx capsule formulation. My
11 understanding is that the Doryx capsule formulation has
12 delayed-release pellets where the delayed-release coating would
13 prevent or slow the release of drug in acid, and then have
14 faster release at higher pH.

15 Q And acid, for example, would be like the environment of the
16 human stomach?

17 A The human stomach environment is acidic, yes.

18 Q And did you ever hear while you were at Warner Chilcot that
19 the reason for that was because immediate release doxycycline
20 hyclate caused people to get upset stomachs?

21 A I'm aware that doxycycline hyclate can cause
22 gastrointestinal distress and nausea.

23 Q And while you were at Warner Chilcot, did you gain an
24 understanding that Warner Chilcot was advertising the
25 delayed-release Doryx capsule as solving the problem of gastric

1 irritation?

2 A My understanding is that -- I really didn't have much to do
3 with the marketing and advertising, but my understanding is
4 that the Doryx capsules had less gastrointestinal distress than
5 Vibramycin.

6 Q Let's see some of those advertisements.

7 MR. WEISBLATT: If we could go to --

8 Q In your book I believe you have a copy of -- and it's on
9 the tab. It should say ITX 7-1-2; 712.

10 And if you want to use the screen, Dr. deVries, I'm
11 also going to put it on the screen in front of you, and this
12 big screen so that you have your choice.

13 Do you have it, the first page?

14 A 712?

15 Q Yes.

16 On the very first page, the first page is a letter, is
17 it not, from Warner Chilcot to the FDA in November 2002
18 regarding advertising and promotion materials for the Doryx
19 capsules. Correct?

20 A Yes. This is a letter to the FDA providing them with
21 copies of promotional pieces for Doryx capsules.

22 Q Are Warner Chilcot's submissions of advertisements to the
23 FDA the type of documents that Warner Chilcot prepares and
24 maintains in its business?

25 A I'm sorry. I don't -- this is a letter that Warner Chilcot

1 would send to the FDA with advertising pieces.

2 Q Would you expect that Warner Chilcot would keep a copy of
3 this letter and its attachments, in its records, in its files?

4 A My expectations is that Regulatory Affairs would keep a
5 copy of this

6 Q Now, the papers of these documents are numbered in the
7 lower right hand number, there are a slew of numbers. But the
8 one I'm going to use is ITX 712, then there's a hyphen and
9 another number. And I'm going to use that other number after
10 712 as the page number, and the one I want you to turn to is
11 712-004.

12 Now, this is an advertisement for the Doryx
13 delayed-release capsules. And it states that the Doryx
14 delayed-release capsules -- and right now I'm at the bottom of
15 the document -- is indicated as an adjunctive therapy for the
16 treatment of severe acne. Right?

17 A I'm sorry, you're reading the advertising piece that was
18 provided to the FDA?

19 Q Yes.

20 A Yes.

21 Q Page 004. That's what it says?

22 A Yes.

23 Q And if I go above that near the picture of the stomach, it
24 says: Doryx is clearly well-tolerated. Right?

25 A Yes, that's the top line.

1 Q And it says that the enteric coated Doryx delayed-release
2 capsules demonstrated less nausea and fewer GI upsets than
3 generic immediate-release doxycycline capsules. Right?

4 A Yes, that's what it says.

5 Q And it claims that the delayed-release Doryx capsules, the
6 drug release is delayed to the small intestine. Right?

7 A Yes, that's what it says.

8 Q And if you go to the next page, 712-005, there is -- the
9 third bullet point talks about fewer gastrointestinal upsets
10 than with generic doxycycline. Do you see that line, Dr.
11 deVries?

12 A Yes.

13 Q And for fewer gastrointestinal upsets it's got a Footnote
14 2.

15 A Yes.

16 Q I apologize for the smallness of the type, Dr. deVries.
17 We're going try to blow it up on the screen.

18 Footnote 2 is a 1988 study by Berger. Is that
19 correct?

20 A Oh. Yes.

21 Q Okay. And in your book, if you go to a new exhibit, which
22 is ITX 79, you can see ITX 79. That is the 1988 study by Dr.
23 Berger, is it not, that's cited in the advertisement, Exhibit
24 712, page 005?

25 A It appears to be the paper. But I have to say that I

1 wasn't involved with the marketing and I'm not -- I haven't
2 really studied this paper, I'm not very familiar with it.

3 Q I understand, Dr. deVries, and I'm not -- other than
4 identifying it I'm not going to ask you any questions about it.

5 A Okay.

6 Q If you go to exhibit again in your book, it's a different
7 exhibit, Dr. deVries, it's ITX 140.

8 Now, that's your signature at the bottom of the page?

9 A Yes.

10 Q And this document ITX 140 is dated January 14th, 1998.
11 Correct?

12 A Yes.

13 Q And you wrote this document to Daniel Deans, the Manager of
14 Business and Technology Development at Faulding?

15 A Yes.

16 Q And the first line, is it, you told Mr. Deans the desired
17 product profile for the Doryx tablet. Correct?

18 A Yes.

19 Q Now, the first bullet point, the overall objective for
20 Warner Chilcot was: To develop a tablet which will be
21 bioequivalent to the Doryx capsule. Correct?

22 A Yes.

23 Q Now, were you in the courtroom when counsel for Warner
24 Chilcot posed a definition of "bioavailability"?

25 A No.

1 Q I'm going to -- I might not quote it exactly but I'm going
2 to try.

3 Bioavailability is the ability of the drug to be
4 absorbed in the body.

5 And when I use that term, that's the definition I want
6 to use, the definition that was used by Warner Chilcot's
7 counsel. Okay?

8 A I'm sorry, that's not --

9 Q Okay. Is that different from your understanding of
10 bioavailability?

11 A My understanding of bioavailability is that it's the rate
12 and extent of absorption of a drug.

13 Q Well, let's use your definition for sure, Dr. deVries.

14 So when I use "bioavailability," I want to use that
15 definition you just gave me. Okay?

16 A Okay.

17 Q All right. Now, from your time at Warner Chilcot, Dr.
18 deVries, the delayed-release Doryx tablet is indeed
19 bioequivalent to the delayed-release Doryx capsule, is it not?

20 A My understanding is that we demonstrated that the tablet,
21 Doryx tablet was bioequivalent to the Doryx capsule.

22 Q Now, in Exhibit ITX 140, the third bullet point from the
23 bottom, you told Faulding that a patented formulation was
24 desired but not required. Right?

25 A Yes.

1 Q From your time at Warner Chilcot, Dr. deVries, did you come
2 to gain an understanding that the function of the
3 delayed-release coating on the Doryx tablets, like the
4 delayed-release coating on the Doryx capsules, was to slow the
5 rate of release of the active ingredient in the stomach and to
6 achieve rapid release of the remaining active ingredient upon
7 entry into the small intestine?

8 A Can you repeat that, please?

9 Q Certainly. I want to talk about the function of the
10 delayed-release coating that's in the Doryx capsules and the
11 delayed-release coating in the Doryx tablets.

12 Would you agree that the function of those two
13 delayed-release coatings was to slow the rate of release of the
14 active ingredient in the stomach, and to achieve the rapid
15 release of the remaining active ingredient upon entry into that
16 small intestine?

17 A I mean, the way I think of it is, a characteristic of a
18 delayed-release product is to have delayed-release in acid or
19 decreased release rate in acid.

20 Q And that was the goal of the delayed-release coating in
21 both the tablets and the capsule.

22 A Both the tablet and the capsule have delayed-release
23 coatings.

24 Q Now, going back to ITX 140, the last paragraph above your
25 signature, Dr. deVries, you told Faulding that the overall

1 project and regulatory strategy will be reviewed and agreed to
2 by Warner Chilcot and Faulding. Correct?

3 A Yes.

4 Q Who at Warner Chilcot reviewed and agreed to the overall
5 project to develop a Doryx capsule to replace the old Doryx
6 tablet?

7 A My recollection is I was one of -- I reviewed and agreed to
8 the overall strategy.

9 Q Did you have to get the approval anyone above you in the
10 Warner Chilcot organization, Dr. deVries?

11 A I don't recall getting -- having scientific review of
12 somebody above me.

13 Q How about a review other than scientific? Was there a
14 review above you regardless of whether it was scientific or
15 not?

16 A I don't recall.

17 Q Now, you closed by telling Faulding that this was an
18 important project. Right?

19 A Yes.

20 Q And one of the copies of ITX 140 you sent to Roger -- I'm
21 going to try to pronounce his last name, Dr. deVries --
22 Boissonneault, B-o-i-s-s-o-n-n-e-a-u-l-t. Correct?

23 A Yes.

24 Q At the time you sent him a copy of ITX 140, he was the
25 president and CEO of Warner Chilcot P LC, was he not?

1 A I don't think he was the CEO at that time. He was my boss.
2 I think he was president but I don't think he was CEO in '98.
3 I don't know.

4 Q So we'll just -- we'll stick with president then --

5 A Okay.

6 Q -- if that's your recollection, Dr. deVries. It's not an
7 issue.

8 Let's go to ITX 725.

9 Dr. deVries, ITX 725 is a Warner Chilcot advertisement
10 for the delayed-release Doryx tablets. Correct?

11 A Well, I see that it's a piece. I'm not sure if it was a
12 piece that was used.

13 Q Okay. Actually I wanted to ask you, if you look at the
14 bottom line of this document, Dr. deVries, it appears to be a
15 special kind of circular or advertisement because the last
16 lines reads: "For sales representative use only. Not to be
17 copied, distributed or left behind, but may be shown to health
18 care professionals."

19 Do you see that?

20 A Yes.

21 Q From your experience at Warner Chilcot, is that a common
22 legend for the type of materials that we see in Exhibit 725?

23 A No, I really wasn't involved in the marketing and promotion
24 of material preparation, so I don't really know --

25 Q Excuse me. Have you --

1 A -- how common that was.

2 Q But have you seen that legend before during your time at
3 Warner Chilcot, Dr. deVries?

4 A I'm aware that there were pieces that weren't to be left
5 behind.

6 Q Now, there is important safety information about Doryx. Of
7 course it's where the small type is. And again, I'm going to
8 have this blown up on the screen in front of you, and this one,
9 or you can look at the paper copy, whatever is more
10 comfortable.

11 And the very first line of the material, Exhibit 725,
12 it says: "Doryx is indicated as adjunctive therapy for severe
13 acne." Right?

14 A Yes.

15 Q Now, does, as a matter of course, does Warner Chilcot keep
16 a copy in its files of the various documents that might be
17 discussed with, for example, health care professionals about
18 its products?

19 A I don't know what the practices are of the marketing and
20 promotional group as far as filing goes.

21 Q Now, the advertisement notes that: "Enteric coated pellets
22 minimize nausea, vomiting and abdominal discomfort," with a
23 Footnote 4. Do you see that?

24 A Yes.

25 Q And if we again go down to the small print which we're

1 going to try to again blow up a bit, Dr. deVries, Footnote 4
2 cites the Berger paper we saw, Exhibit ITX 79.

3 A Okay.

4 Q Do you see that?

5 A Yes.

6 Q Do you agrees that's what it says?

7 A Footnote 4 appears to cite the Berger paper.

8 Q And just to double back for a moment, the Berger paper is
9 about the old Doryx delayed-release capsules. Right?

10 A Yes, the Doryx paper was on the Doryx capsules --

11 Q Now --

12 A -- the Berger paper.

13 Q -- following the launch of the Doryx delayed-release
14 tablets, marketing of the Doryx capsules was discontinued.
15 Correct?

16 A My understanding is that at some point following the tablet
17 introduction of the new product, the tablet, the capsules were
18 discontinued. I don't know how long they overlapped and when
19 that capsules were discontinued.

20 Q In your book you have Exhibit ITX 144, Dr. deVries. Now,
21 Exhibit 144, those are the team meeting minutes of the WC2031
22 Commercialization Team for a meeting that took place April
23 15th, 2004. Correct?

24 A Yes.

25 Q And the subject of the meeting is the Doryx delayed-release

1 pellets in a tablet. Right?

2 A Yes.

3 Q Now, you're identified as a guest of that team, but there's
4 an asterisk there indicating that you were unable to attend.
5 Correct?

6 A That's what the asterisk indicates. I don't remember the
7 meeting, so...

8 Q Not very surprising, it's almost eight years ago, Dr.
9 deVries, and my question is a lot simpler rather than what
10 happened at the meeting in particular other than this document.

11 Were you getting the minutes of the meetings of the
12 WC2031 Commercialization Team that related to the Doryx
13 delayed-release tablet?

14 A I don't remember all the minutes I got, but it's reasonable
15 to think I got copies of the minutes.

16 Q And under "copies," the first person listed under copies is
17 the president of Warner Chilcot, Roger Boissonneault. Correct?

18 A Roger got it. This indicates that Roger was copied.

19 Q Now, in your experience at Warner Chilcot, Dr. deVries, are
20 the meeting minutes of the WC2031 team the type of document
21 that would be kept by Warner Chilcot in its files in the course
22 of its business?

23 A At this time I don't know if there was -- if these kinds of
24 minutes were being archived.

25 Q Okay. Now there's a topic heading on the second page of

1 the document, 144-002, that says "Tablet/Capsule Swap-out
2 Strategy."

3 Do you see that?

4 A Okay.

5 Q And under that section it reads: "Marketing are planning
6 for an aggressive swap-out of the Doryx capsule for the Doryx
7 CPT." Do you see that?

8 A Yes.

9 Q CPT stands for the Doryx tablet?

10 A It's a coated pellet, so it's a tablet.

11 Q And then continuing, Dr. deVries:

12 "The tablet positioning will be to promote that it
13 offers the same benefits as the Doryx capsule with the
14 avoidance of gastrointestinal irritation associated with other
15 doxycycline products." Right?

16 A That's what it says, yes.

17 Q If you could go to --

18 A That's what it says, yes.

19 Q If you could go to in your book the next exhibit, which is
20 ITX 145.

21 Now, ITX 145 is another set of meeting minutes, is it
22 not, of the WC2031 team for Doryx delayed-release tablet?

23 A This is a different team than the previous. This is a
24 project development team. The previous was commercialization.

25 Q Thank you.

1 And you're the first listed team members, but again
2 there's an asterisk by your name for this particular meeting
3 you were unable to attend. Right?

4 A Yes.

5 Q Whether it was for the project team or the
6 commercialization team, were you getting minutes from all of
7 the various teams of the WC2031 Doryx delayed-release tablet
8 project?

9 A Well, I expect that I was getting the Project Development
10 Team minutes and that I was copied on the Commercialization
11 Team minutes.

12 Q And again, we see ITX 145, the first copy that's listed
13 went to the president of Warner Chilcot?

14 A It went to Roger Boissonneault. I don't know his title at
15 the time.

16 Q Now, in the executive summary of the document, ITX 145, the
17 fourth bullet point is that the FDA has suggested that the
18 Doryx capsules remain available once the Doryx tablet is
19 launched. Correct?

20 A That's what that summary says, yes.

21 Q Do you recall why the FDA suggested to Warner Chilcot that
22 the old capsules remain on the market after the tablet was
23 launched?

24 A No, I'm not aware of why the FDA asked that.

25 Q Now, if we go to another exhibit in your book, Dr. deVries,

1 which is ITX 142, these are the May 13th, 2004 meetings of the
2 WC2031 Commercialization Team meeting. Correct?

3 A Yes.

4 Q And you were a guest at that team meeting, May 13th, 2004.
5 Right?

6 A That's what this suggests.

7 Q Now, in 2004 do you recollect that the person who got the
8 first copy is indeed at this point the president of Warner
9 Chilcot?

10 A I see that Roger again was copied on these minutes.

11 Q And if we go to the third -- excuse me -- yes, the second
12 page of the document, at the very top, the swap-out strategy,
13 do you have that?

14 A Yes.

15 Q In May of 2004 the plan was for an aggressive swap-out of
16 the Doryx capsule for a Doryx tablet at the wholesale level?

17 A Okay.

18 Q And the retail supplies of the capsule will be allowed to
19 sell out?

20 A I see where it says that.

21 Q Is that your recollection of what actually happened, Dr.
22 deVries?

23 A You know, my recollection is that there was a variety of
24 strategies discussed on how to introduce the new tablet and
25 what to do with the capsules, and that there was various

1 discussions about it. And I really wasn't involved in that
2 area so I didn't keep track. I'm just aware that there was a
3 variety of discussion by the marketing and commercialization
4 folks.

5 Q If you go to the next page in the document, Dr. deVries,
6 ITX 142-003, there is a slide at the top, "Doryx Tablet Launch
7 Plan." Do you see that?

8 A Yes

9 Q And the second bullet point explains that the launch plan
10 has four elements. Right?

11 A The second bullet says the launch plan has four elements.

12 Q And the first listed element of the launch plan was to swap
13 out the old Doryx delayed-release capsules to preserve
14 franchise. Right?

15 A Well, the number one says: Swap out the capsules to
16 preserve the franchise.

17 Q If you would go to Exhibit ITX 129. Now, this is a
18 document that has had some handwriting at the top. But first I
19 want to get to -- if we can first get to the box, the title of
20 the document is Doxycycline Hyclate Delayed-release Tablets,
21 Product Development of 15 December, 1997. Correct?

22 A Yes.

23 Q And then above that on the first page is some handwriting.
24 The handwriting reads: "Provided to Warner Chilcot, Danny,"
25 then MTG, what looks like to me like the 8th, December of 1997.

1 Would you agree?

2 A Oh. Okay. I never knew what that was. I guess it looks
3 like an 8, yeah.

4 Q Now, the Danny in that sentence is Daniel Dean. Right? He
5 was the man who we saw who's Faulding's manager of business and
6 technology development?

7 A That could -- there -- Dan was -- there was a Danny Deans,
8 and that could be Danny. I do not recall this meeting or
9 receiving the this document.

10 Q Now, in italics under the box title of the document, it
11 says "Protecting Doryx," does it not?

12 A Yes.

13 Q If you go to the second page of the document, ITX 129-002,
14 in the introduction it talks about, Doryx has a reduced
15 incidence of nausea when compared with immediate release forms
16 of doxycycline. Correct?

17 A Yes.

18 Q And the report proposes experimental work to assess the
19 feasibility of preparing tablets that are bioequivalent to the
20 capsules. Right? The middle paragraph of the introduction.

21 A Yes, okay. That's what it says.

22 Q And the key -- under "Feasibility Study Objectives," the
23 key requirement was to produce a product that was AB-rated
24 equivalent to Doryx capsules. Right?

25 A You know, this is a Faulding document and this is their

1 view of things. That statement is a little bit confusing
2 because it's not possible for the tablet to be AB-rated to the
3 Doryx capsules.

4 Q In terms of bioavailability of the Doryx capsules to the
5 Doryx tablet, how would you describe it, Dr. deVries?

6 A Well, the Doryx capsules and Doryx tablets' bioavailability
7 is the same, but they're not AB-rated. They can't be because
8 they're not the same dosage form.

9 Q Now, if you take a look at ITX 170 -- in fact, instead of
10 that, let's go ITX 168, which should be in your book also.

11 Now, Dr. deVries, this is another doxycycline hyclate
12 delayed-release tablet. And you might have to flip back if you
13 don't remember. This one is dated six days after the ITX 140
14 letter that you sent to Daniel Deans, January 14th, 1998.

15 A I'm sorry. There's a date on 168?

16 Q Yeah. On 168 under "Product Development" you can see 20
17 January 1998. Right?

18 A Okay. And, in this Faulding document --

19 Q In you go back to 140, the date of your letter to Mr. Deans
20 is January 14th, 1998, right, six days before?

21 A Okay. I believe that's what the dates say. If...

22 Q And if we look back to ITX 129, the date of ITX 168 is also
23 after the date -- at least it's written -- that exhibit ITX 129
24 was provided to Warner Chilcot. Right?

25 A Okay. So 120 -- sorry -- 129 is December 8th, '97.

1 Q '97.

2 A Okay.

3 Q Right. Your letter to Mr. Deans is January 14th, '98.

4 Right?

5 A I'm sorry, which one is my letter?

6 Q That's 140. I'm sorry.

7 A 140 is my letter, January 14th, '98. Okay.

8 Q And then six days later we have the date that's on ITX 168.

9 Right?

10 A Yep.

11 Q Okay. Now, we see on the next page, 002, there's a
12 introduction again similarly to what we saw before, but in ITX
13 168 it's at page 2. Correct?

14 Do you have the introduction?

15 A I'm not really familiar with this document, it's a Mayne --
16 it's a Faulding document.

17 Q In the introduction of the document, Dr. deVries, it
18 states, the second paragraph: "The tablet is to be used as an
19 anti-generic strategy should generic competition be launched
20 against the current doxy capsules." Right?

21 A The current Doryx capsules.

22 Q The current Doryx capsules, sorry.

23 That's what it says. Right?

24 A Yes. And this is -- I'm not sure that I've seen this
25 document. This is a Faulding internal document.

1 Q Well, it's a Faulding internal document. And if I'm not
2 mistaken, Faulding became Mayne Pharma in some way, Dr.
3 deVries, do you know that?

4 A Yes, they became Mayne.

5 Q And Mayne Pharma is a Plaintiff in this case. Did you know
6 that?

7 A Yes.

8 Q So Warner Chilcot and Mayne Pharma, the successor to
9 Faulding, are both Plaintiffs in this case. Right? You know
10 that, don't you?

11 A Okay.

12 Q So now if we go to page 168-003 under "IP-legal issues,"
13 you see the statement: "A patented formulation is desired but
14 not required." Correct?

15 A Yes.

16 Q Now, if I'm not mistaken, that's exactly what you told Mr.
17 Deans six days before?

18 A That was in 140?

19 Q In fact, its word-for-word the same, is it not?

20 A Yes, it's the same words. Yes.)

21 Q Now, if you go to ITX 170 -- and this is a Faulding
22 document -- "Danny Deans' oversees seas trip. UX/US May of
23 1998." Correct?

24 A That's what it says at the top, yes.

25 Q If you go to the second page, ITX 170-002, there are some

1 numbered paragraphs there, and paragraph number four is, quote:
2 It is their intention to discontinue the Doryx capsule as soon
3 as the tablet is available to eliminate generic competition.

4 Correct?

5 A I see that written there, yes.

6 Q The "their" in that sentence is Warner Chilcot, is it not,
7 Dr. deVries?

8 A You know, this again is a document that I would not have
9 had access to, it's not one I've seen. But that sentence does
10 suggest that the "their" is Warner Chilcot.

11 Q And in the next sentence, Number 5, it stays, quote: They
12 do not expect to have any increase in sales as a part of the
13 switch, merely as an anti-generic strategy. End quote.

14 Correct?

15 A Yes, it says that.

16 Q And the "they" in that sentence appears to be Warner
17 Chilcot, would it not, Dr. deVries?

18 A It would appear that.

19 Q Now, do you recall, Dr. deVries, at some point Warner
20 Chilcot was notified that Mayne Pharma -- Mayne Pharma had some
21 evidence that a blister pack, a blister pack of the Doryx
22 capsules that they had seen, what they referred to as a
23 failure. Does that ring any bells for you?

24 A I'm sorry. That Mayne had a failure --

25 Q Mayne Pharma saw a failure of a blister pack of the

1 capsules, and they notified Warner Chilcot of the failure they
2 had seen. Do you recall that?

3 A I'm a little -- I don't remember that Mayne was packaging
4 the blisters, we were doing that. And I don't have a specific
5 recollection of -- I'm aware that there were stability issues
6 with the capsule in blister packaging.

7 Q Is that something that you would have been informed of in
8 January 2002, Dr. deVries, that they had been seeing this
9 problem with the blister pack?

10 A I would have been informed of stability issues. I was
11 fully aware that the dissolution acid stability profile for the
12 capsules was less than ideal and that we were -- that it was a
13 problem, and if there was a stability failure, I would have
14 been informed.

15 Q Today as you sit here, today, Dr. deVries, do you remember
16 the details you were given about that failure?

17 A I don't remember the details.

18 Q Okay.

19 MR. WEISBLATT: I wonder if we could take ITX 176 at
20 page 5 and put it on the screen.

21 Q It also should be in your book, Dr. deVries.

22 MR. SCAMBIA: Counsel, do you have a copy for me,
23 please, a full document?

24 MR. WEISBLATT: I don't.

25 Q Is there a copy of it in your book?

1 A I'm sorry. I have 175 and 177.

2 MR. WEISBLATT: So I think I'm going to use it just to
3 try to refresh her recollection, your Honor, in accordance with
4 the Rules of Evidence. I'm not going to try to introduce it.

5 THE COURT: Refer it to her and let her look at it and
6 see if it refreshes her recollection.

7 MR. WEISBLATT: Thank you.

8 Q If you look at the second bullet point January --

9 A I'm sorry. This is a document? What is this?

10 Q I'll explain it to you. As far as I can tell, this is a
11 document that was produced out of Mayne Pharma's files.

12 A Okay.

13 Q Okay? It's titled, if that will help you, Dr. deVries, is
14 "Doryx Capsule," and then FP-240. And it's a series --

15 A FP-240?

16 Q FP-240. That's on the cover. And then the fifth slide is
17 this document that I'm showing you here.

18 And the first bullet point is January of '02: Failure
19 of blister, and it gives some numbers, WC notified. Agreed to
20 report OOS in annual report.

21 Do you see that?

22 A Yes.

23 Q Does that help refresh your recollection that Warner
24 Chilcot was notified in January of 2002 that there had been a
25 failure of capsules, of the Doryx capsules, a blister pack?

1 A You know, I'm generally aware that the Doryx capsule
2 stability was problematic and challenging and that there were
3 stability failures. I can't tell what strength this is --

4 Q So this does not help refresh your recollection of this
5 particular --

6 A Not specifically. Again, I'm generally aware of the
7 capsule stability problems.

8 Q In you go down to October of 2002 bullet point in this
9 document, Dr. deVries, it mentioned WC or Warner Chilcot
10 volunteered to cease distribution of sample packs, blisters.

11 Do you see that?

12 A Yes.

13 Q Does that help refresh your recollection about what
14 occurred in terms of the blister pack issue?

15 A My understanding is that the stability in the blister was
16 not adequate to support distribution and the expiration date.

17 Q If you go to the bullet point that's April of '02, there is
18 mention of a -- the commencement of a desiccant study in
19 bottles.

20 A Yes.

21 Q Do you recall in April 2002 the commencement of a desiccant
22 study of the Doryx capsules in bottles?

23 A I don't recall the exact timing, but I do recall starting a
24 study where we add desiccant to the bottles to evaluate the
25 stability of that package, that container closure.

1 Q And do you recall as a result of that work you just
2 described that the Food and Drug Administration set the
3 expiration period of the capsules to be 24 months when they
4 were in a 60-capsule bottle? Do you recall that?

5 A I'm sorry. The process is that we provide the agency with
6 data supporting the container closure, with data supporting the
7 proposed expiration date, and then the FDA agrees to that.

8 Q Do you recall using that setup of the procedure, Dr.
9 deVries, that as a result of the desiccant study, Warner
10 Chilcot went to the FDA, asked for a 24-month expiration date
11 for the 60 Doryx capsules in a bottle, and then the FDA agreed
12 to that 24-month expiration date?

13 A My understanding is that the expiration date on the Doryx
14 capsule packages was 24-months.

15 Q Okay.

16 A And that the FDA agreed to that.

17 MR. WEISBLATT: Your Honor, we had informed the
18 Plaintiffs that we had put a document that was undated and
19 unsigned on our exhibit list, and I located a signed and dated
20 copy. The content of the document is the same.

21 THE COURT: All right.

22 MR. WEISBLATT: And I wanted to use that one instead
23 of the 175 -- it's ITX 175, and I wanted to substitute the
24 signed letterhead copy for our exhibit list.

25 THE COURT: Is there any objection to that?

1 MR. WEISBLATT: There wasn't yet.

2 MR. SCAMBIA: No objection, your Honor.

3 THE COURT: Then go ahead and substitute it in.

4 MR. WEISBLATT: Thank you, your Honor.

5 If we could go to ITX 175.

6 BY MR. WEISBLATT

7 Q Do you recall, Dr. deVries, at one point there was a
8 limited recall of certain batches of the Doryx capsules?

9 A My understanding, there was a recall of the 75 milligram
10 capsules.

11 Q If you look in your book, it should be Exhibit ITX 175.

12 A Okay.

13 Q This is a letter from Warner Chilcot to its customers about
14 a voluntary recall of certain listed lots of the Doryx
15 capsules?

16 A Yes.

17 Q And then if you look at the last several sentences in that
18 first paragraph: (Reading) The data submitted in the
19 supplement fails to support a 24-month expiry period. Right?

20 A Yes.

21 Q And the recall was being initiated as a precaution due to
22 limited stability data. Right?

23 A That's what the letter says, yes.

24 Q That no stability failures have been reported for the drug
25 lots in distribution. Correct?

1 A Yes.

2 Q I wonder if you could go to Exhibit 177 in your book,
3 Doctor. Exhibit 177.

4 A Yes.

5 Q Do you have it?

6 A Yes.

7 Q This is a document that was produced to us by Warner
8 Chilcot, that's the WC number you see underneath the little
9 sticky. It reports a visit by Mayne Pharma August 11th, 2008,
10 and it lists quite a few people there. Do you see that on the
11 first page?

12 A The top says, "Mayne visit, August 11, 2008."

13 Q Right. And it says, "Mayne Pharma International," and it
14 lists quite a few names. Correct?

15 A Yes.

16 Q From your time at Warner Chilcot, those are all people who
17 work for Mayne Pharma, are they not?

18 A My understanding is they work for Mayne, yes.

19 Q And it mentions -- the third person down is Stefan Lukas,
20 and it says, "Tina's primary contact."

21 A Right.

22 Q Do you know who at Warner Chilcot would keep notes of the
23 minutes of a meeting between Warner Chilcot and Mayne Pharma in
24 August of '08?

25 A I don't believe that these are minutes of a meeting.

1 Q Okay. Do you know, in looking at ITX 177, do you know what
2 it is, Dr. deVries?

3 A My recollection is that this is a document that I prepared
4 for -- I'm not sure if it was for Lee or for Lynn, but someone
5 in Warner Chilcot was visiting Australia and that this was a
6 document that I prepared as a summary of the issues, of the
7 project.

8 Q And when you prepared this summary, you attempted to be
9 accurate in your description of the various items that are in
10 ITX 177, to the best of your ability?

11 A Yes.

12 Q Now, the Doryx capsules remained on the market in the
13 United States during and after that limited recall that we saw
14 in the earlier letter to the FDA?

15 A Yes.

16 Q And Warner Chilcot continued to promote Doryx capsules
17 during and after the recall, didn't they?

18 A Well, I mean, during the recall those lots were removed
19 from the market.

20 Q But other than those lots being removed from the market, it
21 was business as usual with the Doryx capsules, was it not?

22 A Well, yes, there were Doryx 100 milligram and 75 milligram
23 capsules on the market.

24 MR. WEISBLATT: I no further questions, your Honor.

25 THE COURT: All right. Cross-examination.

1 MR. SCAMBIA: Yes, Judge.

2 May I approach, Judge?

3 THE COURT: Yes, you can.

4 CROSS-EXAMINATION

5 BY MR. SCAMBIA:

6 Q Good afternoon, Dr. deVries.

7 Now, during the examination of counsel, there was
8 reference to certain stability studies that were done with the
9 capsule product. Correct?

10 A Yes.

11 Q Can you turn to ITX 681, please, in your book.

12 And can you identify that for us, please?

13 A So, this is a cover letter from Regulatory affairs to the
14 FDA which is providing an amendment to a supplement for the
15 Doryx capsule 75 milligram supplement, and it's providing
16 stability data to the FDA.

17 Q And can you turn to production page 66188, please. And can
18 you tell us what's set forth on this page?

19 A So, this page is a summary of the Doryx 75 milligram
20 capsule stability study, so it indicates what the product
21 that's being studied, there's a description of the package,
22 including the container closure, including the desiccant, and
23 then there's also the description of the storage conditions.
24 In this case it's 40 degrees centigrade, 75 percent relative
25 humidity, which is an accelerated stress condition.

1 Q And how many capsules were in this container?

2 A Sixty.

3 Q And why was this testing done?

4 A This was a stability test of the package -- of the
5 container closure, Doryx capsules containing the desiccant.

6 Q Okay. And turn, if you would, to the next page now,
7 please, Dr. deVries. And what appears at this page?

8 A So, these are the detailed stability testing results for
9 that study.

10 Q And can we focus on the line that begins with "Acid
11 resistance" for a few moments.

12 And can you tell the Court what's set forth in that
13 line?

14 A So, this is acid resistance, which is the dissolution and
15 acid test. And so if you look here at times zero, there was 13
16 percent drug -- of the drug released at time, zero. And at six
17 months there were 70 percent released, which fails to meet the
18 specification for stability because the specification is listed
19 over there on the left, which is not more than 50 percent. So
20 this is showing that this package did not meet the stability
21 specification for acid release in accelerated condition at six
22 months.

23 Q So you're saying the package with the desiccant failed?

24 A Yes.

25 Q So what's your view, Dr. deVries, did the desiccant resolve

1 the dissolution and stability problem with the capsule product?

2 A No, it didn't. I mean, it helped, it helped to add it but
3 it did not solve the problem.

4 MR. SCAMBIA: No further questions, Judge.

5 THE COURT: Anything further?

6 MR. WEISBLATT: Very limited, your Honor.

7 THE COURT: Okay.

8 REDIRECT EXAMINATION

9 BY MR. WEISBLATT:

10 Q Dr. deVries, one of the documents that counsel for Warner
11 Chilcot gave you in your notebook but he didn't go into was ITX
12 662. Could you go to that one very quickly?

13 A Sorry. The notebook that you gave me?

14 Q No, the notebook that counsel for Warner Chilcot just gave
15 you.

16 THE COURT: 662? Is that the number?

17 MR. WEISBLATT: Yes -- 682. Sorry. Excuse me.

18 THE COURT: Okay.

19 Q 682 consists of a whole series of similar stability study
20 tests done on the capsules. If you flip through it -- I did
21 already -- and every single page in this document is a
22 stability study done for the capsules.

23 And I wanted to ask you: For these stability studies,
24 would the bottle have included a desiccant for the studies that
25 were done in 682?

1 A Well, we'd have to look at each -- each summary.

2 Q Well, do you know when these studies occur -- and if you
3 just want to pick one I can look at it, Dr. deVries -- but when
4 these studies are done in the bottle, package size 60, aren't
5 they supposed to be done with the same bottle and the same
6 desiccant and the same liner and everything that's going to be
7 used in the packaging of the product? That's the idea here, is
8 it not?

9 A The stability studies are tested on -- with the container
10 closure of the product.

11 Q Okay.

12 A And this indicates that there was no -- at this time, that
13 these stability studies were conducted there wasn't desiccant
14 in the package.

15 Q Well, so there's no desiccant in the package of these
16 stability studies.

17 If you go to -- I'm just flipping through the dates,
18 some of the dates of the -- at least of the making of the
19 product.

20 So it's your testimony, for example, if you look at
21 page 1 of 17550, that expiration date of the product is 10,
22 2003. And it's your testimony that at that point there was no
23 desiccant in the bottle?

24 A Okay, sorry. Which page are you on?

25 Q I'm trying to find different dates. Let me try to find one

1 here --

2 A So the expiration date is set from the date of manufacture,
3 and it was two years.

4 Q All right. So if I go to WC 17596 --

5 A 17596. --

6 Q -- there's a stability initiation date of June 23rd, 2003
7 at the bottom. Do you see that?

8 A Okay. 17596 Yes.

9 Q Can you tell me whether that included a desiccant?

10 A Yes, that included a desiccant.

11 Q Okay. So now, the documents that are ITX 662, Dr.
12 deVries --

13 A This is 100 milligram capsules, yeah.

14 Q The documents that are ITX 662, I looked through every
15 single one of them, and they are all studies of the capsules,
16 and I will make that representation to you. Yet, if you look
17 at the first -- the second paper of ITX 682, the stability
18 information for the capsules is being submitted to the FDA
19 under the NDA for the tablets, is it not?

20 A Yes. This -- this was the part of the NDA for the tablet,
21 and as part of the NDA submission of the tablet, we would be
22 showing comparative stability data. And in order to -- you
23 know, part of the story was the improved stability of the
24 tablet.

25 And in order to -- we would provide the FDA with all

1 the data we had. So in order to show that improved stability
2 of the tablet, we would show the capsule data.

3 Q Yet, in 662, at least your counsel gave you, every bit of
4 that data is for capsules. There is not a page in here about
5 tablets.

6 A Well, the title of Appendix 11 on -- let me see --

7 Q Yes, it's --

8 A 17549 is Appendix 11, is capsule stability data.

9 So it's my expectation that all of the data in this
10 section is capsule stability data.

11 Q And counsel didn't give you an appendix from the NDA for
12 tablets about the stability data for the tablets themselves,
13 did he? This is the only one you have. Right?

14 A This is the only one in this notebook.

15 MR. WEISBLATT: I have no further questions, your
16 Honor.

17 THE COURT: Thank you.

18 Anything further?

19 MR. SCAMBIA: Nothing further, Judge.

20 THE COURT: You can step down. Thank you, doctor.

21 (Witness excused.)

22 THE COURT: We'll adjourn for the day.

23 Who is our next witness, tomorrow morning?

24 MR. WEISBLATT: Your Honor, the next witness, as I
25 explained, it's going to be Dr. Kibbe. He will retake the

1 stand about invalidity. And, your Honor, with your permission,
2 I think especially given the goal, I would like to dispense
3 with all of the qualifications and everything else and just
4 have him retake the stand, be reminded he's under oath and away
5 we go.

6 THE COURT: Well, you already put his qualifications
7 on the record.

8 MR. WEISBLATT: Absolutely.

9 THE COURT: That's fine.

10 MR. WEISBLATT: Thank you.

11 THE COURT: After that we have who else tomorrow?

12 MR. CONDE: We have Dr. McGinity after him.

13 And then --

14 MR. WEISBLATT: That's it.

15 THE COURT: That's it? All right.

16 Then we'll start at nine. We'll see you here 9
17 o'clock tomorrow morning.

18 By the way, as far as a submission for proposed
19 findings of facts and conclusions of law, the sooner you can
20 get those in, the sooner we can get to our work. What would be
21 a realistic estimation from your point of view? I know Monday
22 is a holiday, I don't want to interfere too much. But you tell
23 me.

24 MR. WEISBLATT: Your Honor, I wonder if with your
25 indulgence if I could give you an answer to that tomorrow. As

1 you know, I have a trial immediately following this one.

2 THE COURT: Right. You're out in California, right?

3 MR. WEISBLATT: And I know that this is not going to
4 hold up --

5 THE COURT: In California?

6 MR. WEISBLATT: In California, yes. I know you talked
7 with Judge Sabroth. But if I could have at least this evening
8 to talk with the people of my team --

9 THE COURT: No, go ahead, please do that.

10 MR. WEISBLATT: Thank you.

11 THE COURT: Why don't you both give me an idea
12 tomorrow so I have some idea.

13 Also I understand there's still some disagreement over
14 the exhibits. Is that true?

15 MR. CONDE: Yes, your Honor. There is some
16 disagreement over a few exhibits. I think -- and we haven't
17 exactly exchanged -- we haven't gotten caught up basically --

18 THE COURT: Why don't you do that. We should have
19 some time tomorrow to deal with that.

20 MR. CONDE: In you have two minutes I think we could
21 deal with this one right now, and my guess, the rest of the
22 exhibits, there probably won't be any disputes.

23 THE COURT: Go ahead, let me hear what it is.

24 MR. CONDE: Okay. So as I understand it, the dispute
25 that's left relates to -- I think it's PTX 240 to 41, PTX 244,

1 which relates to dissolution data. There's some other ones,
2 and I'm not going to put them on the record because I think
3 it's probably -- I'm not sure that my notes are quite correct
4 on the precise exhibits, but I think they're all in the same
5 category. And as I understand the issue, is that Impax objects
6 to these exhibits but Mylan does not. And so that let me just
7 briefly explain what they are.

8 When we went through Professor Davies' testimony, as
9 you may recall, we had dissolution data on charts and the
10 results of the dissolution data. And Professor Davies
11 explained that he did dissolution studies on pre- versus
12 post-storage, and he explained generally how he did them and
13 the conditions he did them under and how he stored the samples.

14 And then I said -- I generated a dissolution profile
15 which we talk about, and he put up on the screen the fact that
16 the difference between pre- and post was less than 40 percent.

17 And on that slide we identified all the back-up for
18 that information, all of the actual dissolution data that went
19 into his calculations to show that the difference was that less
20 than 40 percent.

21 And we are asking to admit the back-up data. He
22 didn't specifically show you the documents because they're
23 voluminous, and it's all data, it's not like a lot of talking
24 going on here. And our request is that those be admitted as
25 part of the record.

1 There were no other objections to the documents that
2 themselves during Pretrial Order, as I understand it, and
3 Mylan's counsel does not object to the same type of documents
4 coming in for Mylan's product. So we think the fact that Dr.
5 Davies testified about the dissolution study, that he
6 identified the results of the dissolution study, that that is
7 sufficient to provide a foundation so that the actual data can
8 go into the record.

9 And I guess the only one other thing --

10 THE COURT: Wait, wait.

11 Mylan has no objection to that. Correct?

12 MR. SHATZER: To the exhibits that relate to Mylan's
13 dissolution data, we have no objection to those exhibits.

14 MR. CONDE: I guess only two other points is,
15 Professor Davies wasn't crossed on any of the actual underlying
16 data and I don't think Dr. Kibbe disputes the results of the
17 underlying data. He didn't say anything about it during his
18 non-infringement presentation.

19 THE COURT: Mr. Weisblatt.

20 MR. WEISBLATT: Yes, your Honor, this is a general
21 issue for you, and it doesn't really matter what it is that
22 they seek to admit. They want to admit exhibits that were
23 never mentioned by Dr. Davies on the witness stand, never
24 referred to, that they're merely listed at the bottom of one of
25 his slides.

1 And it is our position --

2 THE COURT: They were part of an exhibit list --

3 MR. CONDE: They were on our trial exhibit list, your
4 Honor, absolutely.

5 MR. WEISBLATT: There's no dispute.

6 The only part of this dispute that requires your
7 Honor's attention is the narrow issue of, if I list an exhibit
8 on the bottom of a slide and the witness never mentions the
9 exhibit, doesn't cite to it, it's completely a cipher during
10 that testimony, whether you're going to admit those into
11 evidence. If you are, you know, it is what it is. But we
12 don't believe that's proper.

13 And there are two other issues other than this that I
14 wanted to get to, but that is the most intractable one. We
15 don't believe that's proper, your Honor.

16 THE COURT: So this underlying -- the charts that he
17 did testify to were based on the underlying data that you're
18 seeking to offer. Correct?

19 MR. CONDE: Yes, your Honor.

20 THE COURT: And there is a reference to it in the
21 chart itself that he did testify about?

22 MR. CONDE: Yes, there's a reference to those specific
23 exhibits that were --

24 THE COURT: Did he testify at all about that
25 reference? Or did he -- he must talked about -- I don't

1 recall, but he must have talked about there was underlying data
2 in order for him to make these conclusions. Correct?

3 MR. CONDE: Yes, your Honor, he testified --

4 THE COURT: Do you disagree with that, Mr. Weisblatt?

5 MR. WEISBLATT: I'm not sure about that, your Honor.
6 I think he testified generally. But the problem that we have
7 is: Yes, I did a dissolution test and I got a bunch of data.

8 THE COURT: Wait a second though. Did all the parties
9 have the data as part of discovery?

10 MR. WEISBLATT: No doubt, your Honor, these have all
11 been --

12 THE COURT: So your experts had the data?

13 MR. WEISBLATT: No dispute.

14 THE COURT: And your experts, if they wanted to test
15 the data they would have had the opportunity to?

16 Yeah, no, I'm going to allow it.

17 MR. WEISBLATT: I understand.

18 THE COURT: I'll allow it. Because it's not unlike
19 summaries in any other case. I mean, it's summaries, and if
20 the witness testifies to a summary that's based on data and
21 everybody had it --

22 MR. WEISBLATT: Your Honor, if he had said, a list --
23 if he had said, listed on the bottom there are the summaries of
24 my data and that's what I relied on, we would not be having
25 this objection right now. It's the complete absence of any

1 comment. But I understand --

2 THE COURT: Isn't there a little reference on the
3 chart that --

4 MR. WEISBLATT: There's a little reference on the
5 chart --

6 THE COURT: Nobody disputes that the data was
7 available. Everybody, all the experts had it during their
8 preparation for the case --

9 MR. WEISBLATT: I understand.

10 THE COURT: -- and the exhibits were listed as part of
11 the trial exhibit list.

12 Okay. I'll allow it.

13 MR. WEISBLATT: Your Honor, there were two other
14 things. They've got on their exhibit list expert reports. We
15 don't believe experts reports should be admitted into evidence.
16 Typically --

17 THE COURT: Nobody is moving in expert reports.

18 MR. WEISBLATT: Yes, they are moving in two expert
19 reports, PTX 637 and PTX 249, and we object.

20 THE COURT: They're experts reports of who?

21 MR. CONDE: Actually, your Honor, we're asking for
22 some of -- let me be more specific. It's ITX 637. So it's an
23 exhibit they put on the exhibit list. And, for example --

24 THE COURT: No, wait, wait. Is it an exhibit or is it
25 an expert report?

1 MR. CONDE: It's an expert report that they put on
2 their exhibit list.

3 THE COURT: Okay. But why would an expert report
4 typically come into evidence?

5 MR. CONDE: Professor Davies was referring to the
6 expert report for a statement that was made in their expert
7 report that he believes supports his positions, so we put it up
8 on the screen and I think he talked about the specific
9 paragraph. So we're asking for selected pages of --

10 THE COURT: But he testified about it.

11 MR. CONDE: He did.

12 THE COURT: Yeah. So it's redundant, it's not
13 necessary. Typically the report itself wouldn't come in unless
14 there's some very good reason. But he testified about it. I
15 mean, so yeah, I'm not going to allow it.

16 MR. WEISBLATT: The last one, your Honor -- again,
17 it's your personal preference -- but the Plaintiffs want to
18 move in, I believe it's a Court Order, I believe it's PTX 546.
19 It might be your Claim Construction Order. That's typically
20 not listed in a trial exhibits list, and I just don't know what
21 your preference --

22 THE COURT: The Order would be part of the record. My
23 claim construction opinion and the Order itself would be part
24 of the record. So if you're concerned about review, certainly
25 the Circuit will have that Order.

1 MR. CONDE: Your Honor, one other thing about the -- I
2 just --

3 THE COURT: And there's been ample testimony about the
4 construction.

5 MR. WEISBLATT: Again, your Honor, it's just the
6 admission into evidence of the Order, that we just --

7 THE COURT: The Order is on the docket.

8 MR. WEISBLATT: Yes, it is, and it would be part of
9 any appeal obviously.

10 MR. CONDE: Your Honor, I just want a clarification on
11 the ITX 637. The reason -- Dr. Davies used that to talk about
12 specific images, so we would like at least certain pages that
13 he discussed that you would have access to so that you can read
14 the transcript along with those pages and images. So we would
15 like to at least submit them so that your Honor can follow
16 along --

17 THE COURT: You say they were Dr. Davies' images?

18 MR. CONDE: Actually they were Dr. Sommer's images,
19 and when he talked about Dr. Sommer's images we used ITX 637
20 because it was easier instead of getting a whole bunch of
21 exhibits, they were all in one place, it was on his exhibit
22 list, so we used that exhibit so Dr. Davies can say: I see the
23 image. This is what I was addressing.

24 THE COURT: Is there any objection to that?

25 MR. WEISBLATT: We have no objection if they want to

1 extract those images they can give whatever the next numbers
2 are.

3 THE COURT: Why don't you work that out, agree on it,
4 and then we'll allow those into evidence.

5 MR. CONDE: Thank you, your Honor.

6 THE COURT: All right. We'll see you tomorrow morning
7 at 9 o'clock. Thanks.

8 MR. SHATZER: Thank you, your Honor.

9 THE COURT: Okay.

10 (At 4:24 p.m., an adjournment is taken to Thursday,
11 February 9, 2012, at 9:00 a.m.)

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